THE EFFECT OF DYNAMIC ANKLE-FOOT ORTHOSES ON THE BALANCE AND GAIT OF STROKE PATIENTS

ANNE ELINA UUTELA

Institute for Health and Social Care Research

University of Salford, Salford, UK

2003

A Thesis Submitted in Partial Fulfilment of the Requirements of the Degree of

Doctor of Philosophy

Table of contents ii

List of figures and tables vi

Declaration x

Copyright xi

Acknowledgements xii

Dedication xiii

Abstract xiv

1 INTRODUCTION 1

1.1 Cerebrovascular accident and stroke 1

1.1.1 Classification 1

1.1.2 Incidence 2

1.1.3 Aetiology 3

1.1.4 Symptoms 3

1.1.5 Recovery 4

1.1.6 Prognosis 6

1.1.7 Rehabilitation 6

1.1.8 Recovery of mobility 8

1.2 Neurobiomechanics of human movement 10

1.2.1 Standing balance 11

1.2.1.1 Balance adaptation and aging 13

1.2.1.2 Balance impairment following stroke 15

1.2.2 Gait 17

1.2.2.1 Gait adaptation and aging 20

1.2.2.2 Gait impairment following stroke 21

i) Muscle strength 21

ii) Joint immobility 24

iii) Spasticity 25

iv) Sensory loss 26

v) Motor dysfunction 26

1.3 Disability: definition and classification 29

1.4 Orthotic intervention 31

1.4.1 Ankle-Foot Orthoses 32

1.4.2 Dynamic Ankle-Foot Orthoses 37

1.4.2.1 Biomechanical and neurophysiological principles of DAFOs 41

1.4.2.2 The use of DAFOs with adult neurological patients 42

1.5 Rationale, hypotheses and aims of the study 44

1.5.1 Rationale 44

1.5.2 Working hypotheses 45

1.5.3 Aims of the research 45

2 METHODS 47

2.1 Subject recruitment 48

2.1.1 Clinical assessment 50

2.1.2 Inclusion criteria 51

2.1.3 Healthy subjects 54

2.2 Experimental design and testing procedures 56

2.2.1 Experimental design 56

2.2.2 Provision of orthoses 58

2.2.3 Testing procedures 60

2.3 Functional assessment and subjective feedback 61

2.4 Balance measurements 63

2.4.1 Balance test data analysis 66

2.4.2 Validity and reliability of the force platform 68

2.5 Gait measurements 70

2.5.1 Step-analyser 70

2.5.1.1 Data analysis 74

2.5.2 Three-dimensional movement analysis system 74

2.5.2.1 Data processing of video recordings 76

2.5.2.2 Transformation of co-ordinate system 79
2.5.3 Accuracy of gait performance 82
2.5.3.1 Data analysis of accuracy measurements 83
2.5.4 Reliability and repeatability of gait measurements 86
2.5.4.1 Data analysis of reliability measurements 87
2.5.5 Additional data analysis during the main phase 87

2.6 Statistics 90
2.6.1 Randomisation 90
2.6.2 Distribution 90
2.6.3 Preliminary studies 90
2.6.3.1 Balance 90
2.6.3.2 Gait – accuracy 91
2.6.3.3 Gait - performance reliability 91
2.6.4 Main phase – Balance data 92
2.6.5 Main Phase – Gait data 92

3 RESULTS AND DISCUSSION 93

3.1 Preliminary studies 93
3.1.1 Results 93
3.1.1.1 Balance test reliability 93
3.1.1.2 Accuracy of gait performance 96
3.1.1.3 Reliability and repeatability of gait measurements 99
3.1.2 Discussion 113

3.2 Main phase – Balance 124
3.2.1 Results 124
3.2.1.1 Subject characteristics 124
3.2.1.2 Functional ability in daily life 126
3.2.1.3 Velocity of sway 127
3.2.1.4 Sway index 136
3.2.1.5 Spectral frequency of horizontal forces 144
3.2.1.6 Distribution of spectral energy (variability) 151

3.2.1.7 Slope of spectral frequency distribution 158
3.2.2 Discussion 164

3.3 Main phase – Gait 175
3.3.1 Results 176
3.3.1.1 Subject characteristics 176
3.3.1.2 Functional ability in daily life 178
3.3.1.3 Spatio-temporal factors of gait 179
3.3.1.4 Segments kinematics of gait cycle 200
3.3.1.5 Correlation between balance and gait 242
3.3.2 Discussion 244

3.4 Main phase - Subjective feedback 258
3.4.1 Results 258
3.4.2 Discussion 264

4 LIMITATIONS **267**

5 GENERAL DISCUSSION, CONCLUSIONS AND FUTURE STUDIES 271
5.1 General discussion 271
5.2 Conclusions 279
5.3 Future studies 280

6 REFERENCES **283**

7 APPENDICES **310**
Appendix I Pilot study 311
Appendix II DAFO fabrication 325
Appendix III Information sheet, evaluation forms, muscle tests and results 335
Appendix IV Balance equations 350

8 ABSTRACT AND PUBLICATIONS **351**

LIST OF FIGURES AND TABLES

Figure 1.1	The gait cycle	19
Figure 1.2	Dynamic Ankle-Foot Orthosis design	39
Figure 1.3	DAFO functional insole	40
Figure 2.1	Summary of the research design	49
Figure 2.2	Reasons for subject exclusion	53
Figure 2.3	Schematic testing procedures	59
Figure 2.4	Force plate	64
Figure 2.5	Balance measurement and signal processing	65
Figure 2.6	Step analyzer	71
Figure 2.7	Gait test in the gait laboratory	73
Figure 2.8	Experimental and filming conditions	75
Figure 2.9	Segmental model of gait performance - APAS™ software	77
Figure 2.10	Absolute spatial co-ordinates	81
Figure 2.11	Kinematic variables	85
Figure 3.1	Linear displacement of right ankle marker	102
Figure 3.2	Linear displacement of right knee marker	103
Figure 3.3	Linear displacement of right hip marker	104
Figure 3.4	Antero-posterior velocity of sway	131
Figure 3.5	Lateral velocity of sway	134
Figure 3.6	Sway index in a-p plane	138
Figure 3.7	Sway index in lateral plane	141
Figure 3.8	Mean spectral frequency in a-p plane	146
Figure 3.9	Mean spectral frequency in lateral plane	149
Figure 3.10	Variability of spectral frequency (a-p)	153
Figure 3.11	Variability of spectral frequency (lat)	155
Figure 3.12	Slope of spectral frequency (a-p)	160
Figure 3.13	Slope of spectral frequency (lat)	163
Figure 3.14	Gait velocity (all subjects)	181
Figure 3.15	Individual differences in velocity for the experimental group	182
Figure 3.16	Gait velocity (control and experimental groups)	184
Figure 3.17	Differences in velocity between the DAFO and shoes	185
Figure 3.18	Representative normality data	186
Figure 3.19	Individual differences in stride length	190

Figure 3.20	Individual differences in step length	193
Figure 3.21	Individual differences in cadence	196
Figure 3.22	Individual differences in single stance duration	199
Figure 3.23	Foot angular displacement	203
Figure 3.24	Shank angular displacement	209
Figure 3.25	Thigh angular displacement	215
Figure 3.26	Foot angular velocity	221
Figure 3.27	Shank angular velocity	229
Figure 3.28	Thigh angular velocity	236
Figure 3.29	Correlation between gait and balance	243
Figure 3.30	Subjects' opinion of donning and doffing the DAFO	259
Figure 3.31	Subjects' opinion of daily use of the DAFO	261
Figure 3.32	Subjects' opinion of walking with the DAFO	263

Table 2.1	Subject details (healthy subjects)	55
Table 2.2	Subject details (control group)	57
Table 2.3	Subjects details (experimental group)	57
Table 2.4	Demographic details of subjects participating in the main study	58
Table 2.5	Testing procedures	61
Table 2.6	Testing design for reliability tests	86
Table 3.1	Within-test reliability	94
Table 3.2	Between-test reliability	95
Table 3.3	Repeated digitisation of markers' linear displacement	97
Table 3.4	Repeated digitisation of 3-D co-ordinates	100
Table 3.5	Reliability of gait data (linear displacement)	106
Table 3.6	Within-test reliability (linear velocity)	109
Table 3.7	Within-test reliability (segment displacement)	110
Table 3.8	Within-test reliability (segment velocity)	111
Table 3.9	Within-test reliability (joint displacement)	112
Table 3.10	Within-test reliability (joint velocity)	113
Table 3.11	Demographic details of subjects in the balance tests	125
Table 3.12	Demographic details (healthy elderly)	126
Table 3.13	Summary of ADL tests (control group)	128
Table 3.14	Summary of ADL tests (experimental group)	129

Table 3.15 a	Statistical tests of the velocity of sway (a-p)	132
Table 3.15 b	Statistical tests of the velocity of sway (lat)	135
Table 3.16 a	Statistical tests of sway index (a-p)	139
Table 3.16 b	Statistical tests of sway index (lat)	143
Table 3.17 a	Statistical tests of mean spectral frequency (a-p)	147
Table 3.17 b	Statistical tests of mean spectral frequency (lat)	150
Table 3.18 a	Statistical tests of spectral frequency variability (a-p)	154
Table 3.18 b	Statistical tests of spectral frequency variability (lat)	157
Table 3.19 a	Statistical tests of the slope of spectral frequency (a-p)	161
Table 3.19 b	Statistical tests of the slope of spectral frequency (lat)	162
Table 3.20	Balance results for left and right sided hemiparetics (exp. group)	165
Table 3.21	Demographic details of subjects in the gait tests	177
Table 3.22	Subjects' ADL scores	178
Table 3.23	Statistical tests of gait velocity differences (experimental group)	187
Table 3.24	Statistical tests of gait velocity differences (fast and slow walkers)	188
Table 3.25	Stride length	189
Table 3.26	Statistical tests of stride length differences	191
Table 3.27	Step length	192
Table 3.28	Statistical tests of step length differences	194
Table 3.29	Cadence	195
Table 3.30	Statistical tests of cadence differences	196
Table 3.31	Single stance phase	198
Table 3.32	Statistical tests on single stance phase duration differences	200
Table 3.33	Statistical tests on differences in minimum foot displacement	207
Table 3.34	Differences in minimum foot displacement (fast and slow walkers)	207
Table 3.35	Statistical tests on differences in minimum shank displacement	212
Table 3.36	Differences in minimum shank displacement (fast and slow walkers)	213
Table 3.37	Statistical tests on differences in minimum thigh displacement	218
Table 3.38	Differences in minimum thigh displacement (fast and slow walkers)	218
Table 3.39	Statistical tests on differences in minimum foot velocity	224
Table 3.40	Differences in minimum foot velocity (fast and slow walkers)	224
Table 3.41	Statistical tests on differences in maximum foot velocity	226
Table 3.42	Differences in maximum foot velocity (fast and slow walkers)	226
Table 3.43	Statistical tests on differences in minimum shank velocity	228

Table 3.44 Differences in minimum shank velocity (fast and slow walkers) 232
Table 3.45 Statistical tests on differences in maximum shank velocity 233
Table 3.46 Differences in maximum shank velocity (fast and slow walkers) 234
Table 3.47 Statistical tests on differences in minimum thigh velocity 239
Table 3.48 Differences in minimum thigh velocity (fast and slow walkers) 240
Table 3.49 Statistical tests on differences in maximum thigh velocity 241
Table 3.50 Differences in maximum thigh velocity (fast and slow walkers) 241

Appendix I

Figure A1.1 Foot displacement on the affected side (subject B) 322

Table A 1.1 Demographic details of subjects 312
Table A 1.2 Testing procedures 315

Appendix II

Figure A 2.1 Foot support during negative casting 325
Figure A 2.2 Accurate outline of foot using carbon paper 326
Figure A 2.3 Outline of foot is used as a template for a 'pelite' sponge rubber board 326
Figure A 2.4 Constructing a plaster build-ups moulded under arches and toes 326
Figure A 2.5 Finalising footboard negative 326
Figure A 2.6 Casting procedure around ankle 327
Figure A 2.7 Casting procedure around foot 327
Figure A 2.8 Final cast negative – model 327
Figure A 2.9 Dried positive cast – smoothing 327
Figure A 2.10 Heated homopolymer polypropylene is stretched over the positive cast 328
Figure A 2.11 Finalised stretching stage 328
Figure A 2.12 DAFO with fixed Velcro straps 329
Figure A 2.13 DAFO fitting 329

Table A 2.1 Summary of subject feedback to orthotist 329

Appendix IV

A 3.1 Formulae used in the measurements of horizontal forces 350

DECLARATION

I, the undersigned declare that :-

No portion of the work referred to in this thesis has been submitted in support of an application for another degree of qualification of this or any other university or other institute of learning.

Anne Elina Uutela

COPYRIGHT

Acknowledgements

Firstly, I would like to thank my supervisor, Professor Peter Bowker, for his support and contribution to this work. I would like to give many thanks for my advisor, Professor Tracey Howe, for her encouragement and advice during this research. I am grateful to the University of Salford for providing funds enabling me to undertake these studies. Many thanks to Gordon Steel of the Bullen Healthcare Group, who is accredited with casting and modifying all splints for the patients. I am also grateful for the financial support provided by Bullens for production of the orthoses.

I am indebted to Dr. Marietta Van Den Linden for her work on the computation of kinematic data processing, and Dr. David Gerret and Dr. Paul Davies for practical help for statistics. Thanks to the Medical Physics Department at Hope Hospital for building and financing the infrabeam system for gait measurement and providing technical support. Consultant Pippa Tyrrell and all of the stuff of the Stroke Unit in Hope Hospital are acknowledged for their collaboration during subject recruitment. Very many thanks to all of patients who where involved in this research.

Finally, my special and most grateful thanks must go to Robert for his constant support and love over the past years.

In memory of my mother and grandmother

ABSTRACT

The present research aimed to assess the effects of a novel type of orthosis, the Dynamic Ankle Foot Orthosis (DAFO), on the balance and gait characteristics of hemiparetic subjects. The DAFO is a low splint with a custom-moulded insole, which is believed to support foot alignment, ankle supination-pronation and provide minimal restriction of the ankle joint flexion-extension. It was hypothesised that DAFOs improve motor behaviour after stroke involving the acquisition of standing balance (hypothesis I) and gait (hypothesis II) compared with using shoes. It was proposed that users' subjective opinions of DAFOs would support the findings of the device's ability to modify human performance such that they are beneficial when used as a part of rehabilitation management for stroke patients (hypothesis III).

Twenty-two stroke subjects were randomly allocated to experimental (with DAFO and shoes-only) and control (using shoes-only) groups. Subjects followed twelve weeks of experimental trials comprising three data collections. The testing procedure was developed from preliminary work, which involved a pilot study and reliability tests. Standing balance was measured using force-platform apparatus. The parameters investigated were: the velocity and sway index of the CoP, and F(mean), F(sd) and F(slope) of shear forces. Kinematic gait performance was assessed using a 3-D four-camera motion measurement system. The parameters studied were: the gait velocity, stride length, step length, cadence, and single stance phase, together with the minimum/maximum values of the angular displacement and velocity of the foot, shank, and thigh segments in the saggittal plane during two strides. An open questionnaire was used to evaluate subjects' opinions regarding the use of DAFOs.

Overall, the quantitative studies did not identify consistent and statistically significant differences between the two experimental situations for these groups of patients. In the studies of balance, none of the parameter comparisons analysed within- and between- groups achieved statistical significance. In the studies of gait, statistically significant differences were identified for some (but not all) parameters. It is unknown whether any single or combination of balance and gait variables can be used to describe human gait entirely. On this basis, hypotheses I and II were rejected. However, these are tentative conclusions. Thus, difficulties in maintaining the stroke subject cohort number for these studies meant that the analyses probably lacked sufficient statistical

power to detect small but potentially important differences in DAFO mediated actions. Furthermore, in several cases, clear differences in the magnitude of balance and gait parameters between DAFO and shoe users were apparent, and these differences were often consistent with nearer normal levels associated with use of the device (suggesting potentially beneficial influences). Thus, positive effects of the DAFO on lateral velocity of sway and variability of the spectral frequency were evident for some subjects. The gait velocity, stride length and single stance phase were also nearer normal values using DAFOs than without them. In addition, the maximum foot velocity value was improved in the middle of swing phase on the affected side, which may indicate improvement to the ankle dorsiflexion function using these devices.

In contrast to the inconclusive balance and gait findings, the outcome of the questionnaire assessments was clear. The majority of subjects provided very positive feedback with regard to DAFO use. Most subjects expressed confidence in the splint, which they perceived as helpful for their walking ability in day life. Some difficulties were noticed with donning and doffing the DAFO, but the perceived benefits outweighed this consideration. These qualitative studies therefore provide the most convincing evidence to support the idea that DAFOs improve stroke patients' balance and gait, and that this type of orthosis may form a useful adjunct to rehabilitation strategies. However, as the proposals set out for this research were related, acceptance of hypothesis III requires that at least one of the preceding hypotheses be accepted. On this basis, hypothesis III was also rejected.

In conclusion, although this work failed overall to demonstrate a significant effect of DAFOs on the rehabilitation of stroke patients, the anecdotal evidence obtained adds to knowledge in this field. The research identified some parameters of balance and gait, which might be influenced by the device in a beneficial manner. These parameters may be more useful to use in future investigations. The reasons for the discrepant outcomes of the quantitative and qualitative studies are unclear. However, it is suggested that there may be uncontrolled variables within either the patient group or in the DAFOs (or both) which mean that some DAFOs work better than others. It is proposed that further studies of the DAFO are warranted.

1 INTRODUCTION

1.1 Cerebrovascular accident and stroke

Cerebrovascular accident (CVA) is a generic term applied to several clinical syndromes caused by abnormal function of one or more blood vessels supplying the brain. Disorders of the vasculature are common and include cardiac disease, infection, neoplasm, vascular malformation and immunological disorders. Clinically, CVA commonly manifests as a stroke, which is defined by the World Health Organization (WHO) as 'an acute disturbance of focal or global cerebral function with symptoms lasting more than 24 hours or leading to death presumably of vascular origin' (Thorvaldsen *et al.*1995). A neurological insult that produces symptoms of less than 24 hours is termed a transient ischemic attack (TIA) whereas a symptomatic deficit in excess of 24 hours, but which alleviates within seven days, is called a reversible ischemic neurological deficit (RIND).

1.1.1 Classification

Strokes are broadly categorized into two groups: occlusive (due to closure of a blood vessel) and haemorrhagic (due to bleeding from a blood vessel). The most common form of stroke is due to a thrombus occluding the anterior and middle cerebral arteries. These vessels supply the lateral regions of the frontal and parietal cortices, which form the primary sensorimotor regions of the brain, and subcortical structures including the internal capsule, thalamus and basal ganglia. Acute interruption of the blood supply to the brain leads to tissue ischaemia and, within seconds, neural damage. Although the precise nature of this damage is not fully understood, it is believed to involve cellular death due to glutamate-mediated calcium overload (excitotoxicity), redox imbalance (oxidative damage) and energy depletion (mitochondrial dysfunction), which contribute to the neuropathology of stroke by acting in a sequential and reinforcing manner

(Bowling and Beal, 1995; Bittigau and Ikonomidou, 1997; Yamada, 1998; Dirnagl *et al.*, 1999).

1.1.2 Incidence

The first comprehensive epidemiological study in the UK, the Oxford Community Stroke Project, aimed to identify all first-ever strokes and TIAs in a population of 105000 subjects. Over a four year period (1981-85) it was found that there was an annual incidence of 2.0/1000 and that stroke incidence increased exponentially with increasing age (Bamford *et al.*, 1988). More recently, a more extensive study known as the Multinational Monitoring of Trends and Determinants in Cardiovascular Disease (MONICA) conducted by the WHO, monitored stroke incidence and mortality rates for 20 large populations in 11 countries over a 10 year period (Thorvaldsen *et al.*, 1995). This and other surveys have indicated that there are geographic, age and gender differences within and between different countries, which may be due to environmental or social factors, and that the overall incidence of stroke is decreasing (Wolf *et al.*, 1992; Thorvaldsen *et al.*, 1995). Despite this trend, stroke is still a major cause of death and disability in most industrialized countries. For example, recent health surveys indicate that each year over 100,000 people in England and Wales have a first stroke. Of these individuals, two thirds either die within a year or make a complete recovery. The remainder survive with mild to severe disability (Department of Health, 2001). Stroke primarily affects the elderly. Thus, the incidence of stroke up to the age of 30 years is low compared to older adults. Nonetheless, approximately 25 % of strokes occur before the age of 65 and about 55 % below the age of 75 (Leeds Evaluation Unit, 1992; Stroke Unit Trialists' Collaboration, 2001). After coronary heart disease and cancer, stroke is the third most common cause of death in the developed world, and is the leading single cause of severe disability in people living in their own homes (Brust, 1991; Thorvaldsen *et al.*, 1995; Rosamond *et al.*, 1999).

1.1.3 Aetiology

The precise aetiology of stroke is unknown, but is likely to be multifactorial. There may be a genetic predisposition for stroke, as is thought to be the case in other neurological disorders such as Alzheimer's disease, Huntington's disease and amylolateral sclerosis. In addition, factors have been identified that correlate with an increased incidence of both occlusive and haemorrhagic stroke. These include cardiovascular related disorders such as hypertension, atherosclerosis, TIAs (mini-strokes), angina, and atrial fibrillation (Saladin, 1996). Diabetes is also well established as a significant risk factor for stroke, this being either a direct causal relationship, or an indirect effect in conjunction with hypertension (McMillan, 1997). Other factors implicated in the pathogenesis of stroke are smoking, alcohol abuse, physical inactivity, obesity, hyper-cholesterolemia, oral contraceptives and elevated haemoglobin concentrations (Saladin, 1996). It is believed that the recent decline in stroke incidence is attributable to increased awareness and control of these factors (Stegmayr *et al.*, 2000).

1.1.4 Symptoms

Stroke encompasses a wide range of severity. The main reasons for first-time sufferers dying within one month post-stroke are the brain lesion itself, intracerebral haemorrhage, or large cerebral infarcts and associated oedema. Mortality after the first month is more likely to be an indirect result of the initial insult involving, for example, bronchopneumonia, pulmonary embolism or concurrent cardiac disease. Among surviving stroke victims neurological deficits include sensorimotor hemiparesis of the contralateral upper and/or lower limbs. Cognitive deficits may also be apparent post-stroke, including memory, attention, language and visual problems. Lack of control of basic body functions such as incontinence may also arise after a stroke (Herman *et al.*, 1982; Herman *et al.*, 1983; Bonita *et al.*, 1984). All of these deficits can seriously affect quality of life. However, hemiparesis is particularly problematic, as this occurs in 80-90 % of stroke patients (Carr and Shepherd, 1998b).

1.1.5 Recovery

People who survive the initial stages of stroke generally show some improvement over time in their ability to move and perform functional tasks. Recovery after stroke can be broadly categorised as either spontaneous or non-spontaneous (Warlow *et al.*, 2001). Spontaneous recovery is due to cellular reparative processes that occur immediately following the lesion. Non-spontaneous recovery involves neural reorganisation mechanisms that are use- and experience-dependent. Both *in vitro* and *in vivo* studies on animal and human brain have shown that remodelling processes can occur continuously following sensory and motor experience throughout life (Bach-y-Rita, 1990; Lee and van Donkelaar, 1995). Such plasticity within the CNS is believed to enable adaption according to functional demands (Carr and Shepherd, 1998b).

Despite intensive research on the mechanisms for the generation of new cells and neural circuitry, very little is known concerning the regeneration of the complex functions of the nervous system, such as motor program, speech and cognitive processes (Lee and van Donkelaar, 1995). In contrast, over the past decade, there have been considerable advances in understanding the pathophysiological mechanisms which lead to neural destruction in stroke. Perhaps the most striking observation has been that neurons do not die in a matter of minutes to an hour. Even though neurons may cease to function, the brain or spinal cord damage resulting from a stroke can take hours, days or even weeks to reach its maximum extent. The CNS tissue damage progresses over time from the regions that are most metabolically compromised by lack of adequate blood flow to less affected areas (Johansson, 2000).

In recent years anti-hypertensive compounds have been shown to reduce the risk of stroke for high-risk subjects. These drugs include non-steroidal anti-inflammatory drugs (NSAIDS) such as aspirin, diuretics, beta-blockers, calcium channel blockers, angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor antagonists. However, there are no established procedures or pharmacological interventions that

increase the number of independent survivors after a stroke (Sandercock and Willems, 1992; Lipton, 1993; Lindley *et al.*, 1995). Certain drugs can potentially improve the clinical outcome of stroke by counteracting or limiting the severity of neural damage induced at the neurochemical level. Pharmacological studies have been carried out mainly using experimental animal models of stroke, although several clinical trials with human subjects have been and are being undertaken. To date, most of these investigations have provided disappointing results, with treatments having little or even poor therapeutic efficacy. One exception are thrombolytic drugs which, when administered within a few hours of symptom onset, can enhance arterial oxygen and glucose availability to damaged brain tissue, and one compound (tissue plasminogen activator) has been approved for clinical use in acute ischaemic stroke in the US (Chiu *et al.*, 1998). Recently, however, it has been shown that even these compounds can exert deleterious effects on neurons (Traynelis and Lipton, 2001) and are hazardous for some patients, causing increased intracranial haemorrhage (Kaste *et al.*, 2001).

Immediate medical care following stroke is invariably limited to establishing the reason for the incident, and attempting to reduce early mortality and later disability by maintenance of vital functions and minimizing systemic complications (Henon *et al.*, 1995; Pushpangadan *et al.*, 1999). This is often achieved by recognition and treatment of coincidental disorders such as cardiac failure and angina. Most stroke patients receive a computerised tomography (CT) scan that can localize and estimate the size of the lesion and identify intracerebral haemorrhage. Apart from relieving hydrocephalus the only operative procedure for intracerebral haemorrhage is removal of the haematoma. Subarachnoid haemorrhage is treatable by clipping the ruptured aneurysm or, if technically feasible, removal of the malformation. Initial stage stroke patients are closely monitored in order to ensure that the airways are clear and to identify further complications such as pneumonia, the development of which can be exacerbated by immobility, hypoventilation and intubations. Regular and frequent turning and

percussion/vibration techniques are often used to minimize the risk of secretion pooling, atelectasis and bronchopneumonia. In addition, a range of motion exercises and positioning prevent muscle shortening and stiffness. When a patient regains consciousness, most medical institutions recommend active exercise and task-related training (Carr and Shepherd, 1998a; Carr and Shepherd, 1998b; Kwakkel *et al.*, 1999; Forster and Young, 2002).

1.1.6 Prognosis

The great majority of patients who survive the first month after a stroke will improve and, as indicated earlier, many regain normal levels of function. Approximately 45 % become functionally independent (Legh-Smith *et al.*, 1986; Warlow *et al.*, 2001). In the early weeks post-stroke, good prognostic indications include mild deficit, young age, urinary continence, rapid improvement, good perceptual abilities and no cognitive disorders. However, it is difficult to predict outcome with sufficient accuracy as some patients improve unexpectedly, whereas others do not despite having a good predicted prognosis (Bonita and Beaglehole, 1988). The likelihood of independence at six months decreases with increasing age (Lincoln *et al.*, 1990). Studies using clinical measures of recovery (e.g. the Fugl-Meyer scale and Barthel Index) of stroke survivors indicate that most motor recovery occurs before 3 months post-stroke and then plateaus after about 6 months (Wade, 1992). Other studies, using similar methods, have reported recovery up to 5 years post-stroke (Wadell *et al.*, 1987).

1.1.7 Rehabilitation

Rehabilitation strategies, which are implemented throughout the post-stroke period, remain the principle focus for improvement of the patient's condition. The ultimate goal is to enable functional independence such that patients can return to their homes and integrate effectively in community life (Forster and Young, 2002). The primary aims of early rehabilitation are to prevent secondary physical, emotional and intellectual

deterioration, and to prepare the patient and relatives for inevitable alterations in lifestyle. Specialized 'stroke units' with specially trained medical and nursing staff are recommended, as there is strong evidence that this type of care can improve the poor outcomes of stroke. Acute stroke units provide care during the immediate post-stroke period and until the patient is medically stable. When sufficient stability is achieved, rehabilitation strategies, which vary between different stroke units, are often initiated within 48 hours of stroke onset. This initial rehabilitation typically consists of a multidisciplinary approach involving a range of health care professionals (e.g. consultants, psychologists, social workers, speech therapists, physio- and occupational therapists). These Stroke Units are beneficial irrespective of patient age, sex, or variations in stroke unit organization (Johansson, 2000; Stroke Unit Trialists' Collaboration, 2001). For detailed accounts of rehabilitation approaches in acute Stroke Units see (Kaste *et al.*, 1995; Stroke Unit Trialists' Collaboration, 2001).

Rehabilitation beyond the post-acute stages may be implemented by Stroke Units that specialize in such later care, or on a hospital outpatient basis, and in the patient's own home. Recent stroke unit trials confirm the benefits of such units and highlight improvements in longer-term outcomes by engaging community services and/or proved links to continuing rehabilitation (Lincoln *et al.*, 2000). The approaches used remain multi-disciplinary. However, as the subject of the original research described in this thesis concerns orthotic intervention, an aspect of rehabilitation involving physiotherapy, the following information is limited to this discipline. General accounts of multi-disciplinary rehabilitation for stroke patients have been reviewed elsewhere (Forster and Young, 2002; Pollack *et al.*, 2002).

The main physiotherapy method used for stroke rehabilitation in the UK is the Bobath concept (Davidson and Waters, 2000), which is theoretical and has not been tested empirically (Sparkes, 2000). This concept posits that therapy should be aimed at alignment of the body segments via manual facilitation, with an emphasis on achieving

functional symmetry (Davies, 2000). Treatment is usually therapist-led, with a focus on suppression of patient-generated incorrect movement until the normal movement pattern is achieved (Lennon *et al.*, 2001). This Bobath therapy is often supplemented with further rehabilitation, which can include recommendations, counselling, aphasia therapy, and mood modification (Pomeroy and Tallis, 2002). Other physiotherapy treatment strategies deemed appropriate for the patient's condition may include muscle-strengthening exercises, treadmill training and constraint-induced movement, in addition to biofeedback and functional electrical stimulation methods (Forster and Young, 2002).

1.1.8 Recovery of mobility

As gait deficits occur with most stroke patients, re-education of motor control and functional ability are regarded as the main targets for rehabilitation (Jongbloed, 1986; Dombovy, 1991; Ashburn *et al.*, 1993; Duncan *et al.*, 2000). Improved walking function is therefore fundamental to stroke patient rehabilitation (Bohannon *et al.*, 1991) and its achievement depends on several factors, including size and location of the infarct, the patient's age and pre-morbid health (Perry, 1969; Hertanu *et al.*, 1984; Wade *et al.*, 1985). Many patients who recover ambulatory function can only walk slowly (Wade and Hewer, 1987), and often those who can walk indoors require assistance (Chin *et al.*, 1982; Kettle and Chamberland, 1989; Kojima *et al.*, 1990; Perry *et al.*, 1995). In addition, poor physical mobility is negatively correlated with social activities outside the home after the stroke (Niemi *et al.*, 1988; Drummond, 1990; Corr and Bayer, 1992; Kauhanen *et al.*, 2000).

Functional recovery is a key determinant of overall quality of life scores in stroke rehabilitation (Kauhanen *et al.*, 2000). It is generally accepted that the patient should be an active participant in rehabilitation strategies designed to optimise performance of functional actions. Training methods take account of movement, muscle characteristics, environmental context and the pathological nature of the impairment (Pomeroy and Tallis, 2002). General principles of training following stroke include anticipation and

prevention of soft tissue contracture. Other procedures endeavour to mobilize stiff joints or to train endurance and cardiovascular responses by increasing repetitions and distance walking (Forster and Young, 2002). The patient's environment (e.g. their home) can also be modified to achieve a particular outcome (von Koch *et al.*, 1998). The effectiveness of rehabilitation for everyday actions such as walking, standing up and sitting down, reaching and manipulation is based on models of these actions formed from normative data. For a detailed reviews of stroke patient rehabilitation strategies, see Carr and Shepherd (1998b), Kwakkel et al., (1999), Davidson & Waters (2000), Pomeroy and Tallis (2002) and Carr and Shepherd (2003). The traditional view of neurological rehabilitation outlined above posits that such intervention reduces impairment and minimises disability. Thus, using ICF nomenclature, the purpose of rehabilitation is to improve the outcome of the capacity (disability) and performance (handicap), and therefore improve quality of life (Hankey, 1999; WHO, 2001). However, although knowledge of the association between neurological rehabilitation and theories of practice has increased over the last decade, it is still very limited (Lennon, 2001; Lennon et al., 2001). There is intense ongoing debate on major issues such as the efficacy of stroke rehabilitation and which patients are most likely to benefit from intensive rehabilitation (Gresham *et al.*, 1995; Sparkes, 2000). In addition, there is disagreement on which types of rehabilitation are most effective at improving functional outcome (Pomeroy and Tallis, 2002). A better understanding of these relationships together with innovative approaches towards the rehabilitation of stroke patients' walking ability are required to meet the projected rise in individuals affected.

The treatment of acute and rehabilitative stroke patients places a considerable financial burden on health care institutions worldwide. In the UK the cost of stroke to the National Health Service (NHS) is now estimated to be over £2.3 billion per annum, and the total cost of stroke care will rise in real terms by approximately 30 % in less than 25 years. Stroke patients occupy around 20 % of all acute hospital beds and 25 %

of long-term beds. Thus, there is a great need to expand understanding of which elements, or which combination of elements of therapy lead to functional improvements in stroke patients (Ashburn, 1995; Lennon, 2001; Forster and Young, 2002).

The area of orthotic intervention is an aspect of stroke rehabilitation, which, until recently, has been largely neglected (Lennon, 2001; Leung and Moseley, 2003). The influence of orthoses on stroke patients' gait and functional recovery is the focus of the original research described later in this thesis. Certain types of novel orthoses may promote beneficial effects on stroke patients' movement disabilities via neuro-biomechanical influences. Before this subject matter is considered in detail, it is useful to briefly review salient aspects of the neurophysiological and biomechanical basis of human movement, together with the pathological consequences of stroke on patients' balance and gait. The following section also introduces some relevant terminology.

1.2 Neurobiomechanics of human motion

Biomechanics is central to understanding human movement and is defined as the interdiscipline that describes analyses and assesses human movement. However, the relationships between the biomechanical and neurophysiological mechanisms that enable humans to ambulate from one place to another in an upright position are only recently being understood. Controlling bipedal locomotion involves a number of complex tasks. The CNS must generate the locomotor pattern and appropriate propulsive forces. Modulation of changes in the position of the centre of gravity must also occur to coordinate multi-limb trajectories, whilst adapting to changing conditions and joint positions. Furthermore, co-ordination of sensory information from visual, auditory, vestibular and joint receptors must happen in order to account for the viscoelastic properties of muscles (Patla, 1996). All of these events must occur within milliseconds and in conjunction with the coordination of many other bodily functions and movements. In the light of these various subsystems involved in motor control, the nervous system can be seen as being organised both hierarchically and in parallel. Thus, the highest

levels of control do not only affect the next levels down; they can also act independently on the spinal motor neurones. This combination of parallel and hierarchical control allows overlap of functions, so that one system is able to take over from another. Such flexibility may also allow a certain amount of recovery from injury by the use of alternative pathways (Kandell *et al.*, 1991; Johansson, 2000).

Locomotion can require the synchronization of over 1000 muscles, which move 200 bones around 100 moveable joints. Human standing balance and walking develops rapidly from early childhood, and then more slowly, until the adult pattern is achieved at around four years of age (Sutherland, 1997). Throughout adulthood, the gait pattern is essentially steady but then gait speed slows during old age (Prince *et al.*, 1997). The term 'human movement' encompasses maintenance of an upright posture, including balance, walking, running, and many other functional tasks. In the context of this thesis, standing balance and the act of walking are fundamental in relation to the assessment of the orthotic devices studied.

1.2.1 Standing balance

Maintenance of balance in standing is critically importance during daily life. Balance is defined as an ability to maintain equilibrium by positioning the centre of gravity (CoG) over the base of support (over the feet) when standing. The CoG is coincident with the body's centre of mass, the location of which changes as a consequence of alterations in position of the body segments (Murray *et al.*, 1975; Era *et al.*, 1996; Enoka, 2002; Woollacott and Shumway-Cook, 2002). Postural adjustments (termed equilibrium reactions) occur in order to maintain equilibrium (Jones and Barker, 1996). Postural control and its adaptation to the environment are based on muscle tone and postural reflexes, which emanate from the somatosensory system. The CNS activates extensor muscles that counteract the force of gravity, creating postural tone, which then stabilises the body's CoG with respect to the ground. Postural tone occurs mainly at the level of the limbs, back and neck extensor muscles, and the masseter muscle of the jaw. The

main force vector of these muscles counteracts the effect of gravity when an individual is standing (Massion and Woollacott, 1996).

As already indicated, sensory information from the visual, vestibular and somatosensory systems, is central to the neural control of body orientation, with respect to vertical stabilisation against external perturbations. The vestibular system provides information on the position of the head in relation to the gravitational field and through sensing linear and angular acceleration on its motion (Woollacott, 1993). The proprioceptive system, which consists of muscles, joint and cutaneous receptors, provides information on the state of the effector apparatus, such as length and force output of muscle, the position of the body in space and information about environment such as surface. Proprioception provides, therefore, information about movements of the body in relation to the base of support and about the movement and orientation of body segments in relation to each other (Allum *et al.*, 1998). The visual system is also categorised as a proprioceptive system, as it provides information about the environment and the orientation and movement of the body (Lee and Lishman, 1976; Allum *et al.*, 1998). Balance disorders occur when any of the systems described above are disturbed.

Assessment of human balance and posture commonly applies an inverted pendulum model that is acted upon by external forces such as gravity and perturbation (Massion and Woollacott, 1996). Balance control is therefore required continuously, because if gravitational forces act unopposed, the body cannot remain upright (and therefore falls to the ground) (Williams *et al.*, 1997). In a standing position, the CoG of the body never aligns perfectly with the Centre of Pressure (CoP) beneath the feet and needs to be constantly repositioned to maintain equilibrium. In quiet standing, an ankle strategy applies in the antero-posterior direction, whereas a separate hip load/unload strategy by the hip abduction/adductors is the principal mechanism of position adjustment in the medio-lateral direction when standing with feet side by side (Winter, 1995).

Standing balance can be measured using a variety of postural tests that describe balance function and recovery of stability (Browne and O'Hare, 2001). Functional balance tests, such as the 'get up and go' test, or Berg balance scale, are used in both research and clinical settings (Mathias *et al.*, 1986; berg, 1989; Browne and O'Hare, 2001). A popular approach to the measurement of spontaneous postural sway in the laboratory is the use of force platform apparatus (Era *et al.*, 1996; Kinney LaPier *et al.*, 1997). A force platform can measure static or dynamic standing balance by measuring changes in the position of the body's CoG over time. Thus, this and several other balance test methods, can identify and quantify the contribution of different aspect or components of postural control (Niam *et al.*, 1999; Karlsson and Frykberg, 2000; Browne and O'Hare, 2001; Kejonen and Kauranen, 2002).

1.2.1.1 Balance adaptation and ageing

Although the effect of aging on balance has been studied extensively, its influence is complex and still unclear. Balance control systems that decline with age include lower level (e.g. stretch reflex) and automatic long latency (e.g. postural synergies) motor control mechanisms (Williams et.al. 1997). Higher level sensory integrative processes (processing visual, vestibular, and somatosensory information related to body position and stability) also deteriorate with advancing age (Manchester *et al.*, 1989; Quoniam *et al.*, 1995; Winter, 1995; Williams *et al.*, 1997).

Force platform investigations have shown that postural sway clearly increases (movement of the CoP and variability of sway) with advancing age (Teasdale *et al.*, 1991). Blaszczyk *et al.* (1993) commented that the postural stability of older peoples is altered as they are unable to estimate optimal standing position as precisely as the young. At the sensory integrative level, it has been shown that the elderly have great difficulty maintaining effective balance control when there is reduced and/or conflicting sensory (eg. diminished ankle proprioception or erroneous visual cues) information

(Manchester *et al.*, 1989; Winter, 1995). Thus, for example, visual information aids 'fixing' of the body's orientation in space; when visual information is systematically reduced (in a darkened environment), postural sway can increase up to three-fold (Toupet *et al.*, 1992). The proprioceptive system provides information also about the orientation and movement of the body in balance control, and has been demonstrated to deteriorate in the elderly (Lord *et al.*, 1991; Era *et al.*, 1996). The balance control systems of the elderly seem to depend on visual input more than on the other sensory information. Thus, older adults appear to remain within their limits of stability when either visual or somatosensory inputs are reduced, but begin to lose balance when both of these sensory inputs are reduced. Vestibular inputs have been shown to be the predominant source of sensory information available for balance control (Woollacott, 1993; Blaszczyk *et al.*, 2000).

It is also known that the manner in which the body sways over the feet in standing differs between younger and older subjects. Younger individuals tend to sway at the ankle, when the support surface is perturbed (ankle strategy), whereas older adults sway about the hip (hip strategy). It is believed that due to neurophysiological limitations, older adults have more difficulty in generating sufficient ankle torque (Manchester *et al.*, 1989; Blaszczyk *et al.*, 2000; Kejonen and Kauranen, 2002). Furthermore, McClenaghan *et al.* (1995) and Williams *et al.* (1997) have suggested that aging affects the control of lateral stability (hip strategy) more when subjects have a history of balance problems (falls), compared to those who do not, or to young adults.

Following muscle assessment studies of the control of standing balance with elderly people, Inglin and Woollacott (1988) and Lin and Woollacott (2002) also noted that the onset latencies of postural muscles (tibialis anterior and gastrocnemi) are substantially longer in older adults than in young adults. The authors suggested that, during ageing, the ankle dorsiflexor muscles are affected to a greater degree than the ankle platarflexors, and that larger increases in onset latency for voluntary movements occur

as aging proceeds. Using similar experimental approaches, Frank and Earl (1990) and Angulo-Kinzler *et al.* (1998) found that older subjects exhibited a greater variability in the organisation of their postural adjustments, with many subjects displaying differences in the ordering of muscle activation, tonic co-contraction of agonist and antagonist muscles, and/or activation of postural muscles following the activation of the voluntary muscle group. These ranges of postural adjustments were accompanied by longer reaction times and smaller centre of pressure displacements under the feet when subjects was asked to push or pull an object.

Elderly people exposed to perturbations of balance on a force platform exhibit deficits in temporal sequencing and in the relative strength of distal (ankle) and proximal (hip) synergistic muscle activation (Woollacott *et al.*, 1986). In addition, Quoniam *et al.* (1995) reported that older individuals tend to underestimate the state of disequilibrium of the body, which is translated into underestimation of the amplitude and/or velocity of the muscular responses produced (Quoniam *et al.*, 1995).

Although postural sway has been found to increase with age there is considerable variability among subjects, and its relation to functional ability is not clearly established (Winter, 1995). Several factors may affect balance in the elderly including the subjects' specific pathology. In addition, those with a relatively inactive lifestyle in general undergo greater degeneration of neural and/or musculoskeletal systems (Horak *et al.*, 1989). Reduced sensation, leg muscle weakness and increased reaction times appear to be important factors associated with postural instability in the elderly (Lord and Castell, 1994; Sherrington and Lord, 1997).

1.5.3 Balance impairment following stroke

Stroke invariably leads to postural imbalances in affected individuals (Winter, 1995). Several aspect of balance control in standing are compromised following stroke. Indeed, some patients have difficulties remaining upright (Partridge *et al.*, 1993), or can only

stand for short periods of time (Bohannon *et al.*, 1993). For those who can stand, the posture is typically much less steady than that of healthy subjects, and is asymmetrical, with less weight being carried on the affected leg (Dettmann *et al.*, 1987; Kirker *et al.*, 2000). Common balance-related deviations identifiable following stroke are greater sway trajectories and velocities during quiet standing (Lehmann *et al.*, 1987; Lee *et al.*, 1988). In static standing tests of CoP measured with a force platform, stroke patients' weight is distributed asymmetrically, with a shift of the CoP towards the unaffected side (Shumway-Cook *et al.*, 1988; Sackley, 1991); an increase in CoP variability is also evident (Shumway-Cook *et al.*, 1988; Winstein *et al.*, 1989). In addition, stroke patients present with higher CoP variability than healthy elderly subjects (Winter, 1991b) with up to three-fold increases in velocity of sway (Briggs *et al.*, 1989; Nadeau *et al.*, 1999b; Walker *et al.*, 2000).

Differences between stroke patients and healthy subjects are also apparent during tasks that require active changes in the position of the CoP, when subjects are asked to lean the body (as far as possible) in specific directions, without altering their foot position. Thus, stroke patients are unable to move their CoP as far as healthy controls, in either the antero-posterior or lateral directions (Dettmann *et al.*, 1987; Goldie *et al.*, 1996). Lee and colleagues (1988) found that the maximum sustainable reach in a-p and lateral directions was lower for hemiparetic stroke patients than for elderly, healthy subjects.

Stroke patients also experienced more difficulty in relating stability when their balance was moved (pushed) towards the affected side compared to control subjects (Wing *et al.*, 1993). In order to offset postural instability, healthy people can consciously alter muscle contraction. However, muscle onset latencies may be slowed or delayed following stroke, which affects such individual's ability to respond quickly to a sudden potential loss of balance and patients rely on the unaffected leg (Carr and Shepherd, 1998a; Kirker *et al.*, 2000).

Because of decreased equilibrium, stroke patients are more prone to falling than are healthy individuals. Indeed, falling has been reported as a major cause of morbidity, hospitalization and mortality in stroke patients (Jorgensen *et al.*, 2002). Furthermore, stroke patients who experience a fall present later with poorer balance and physical function than stroke patients without falls (Teasell *et al.*, 2002). The loss of balance, misjudgement of distances during movements, and foot dragging during walking, turning, and sit-to-stand were reported as causal factors in relation to falls (Hyndman *et al.*, 2002).

In recent years, several studies have addressed the effects of new (and current) rehabilitation techniques aimed at improving balance recovery after stroke (Carr and Shepherd, 2003). Specific therapy methods designed to retrain patients' standing balance after stroke have been evaluated, including the measurement of the effects of 'compelled shoe lift', where mechanical lift under the unaffected foot was used to increase subjects weightbearing on the affected leg (Chaudhuri and Aruin, 2000). Another approach involves visual feedback balance training with computer assisted force plate equipment (Walker *et al.*, 2000); both of these therapy methods have provided encouraging findings. The use of AFOs is a therapy method that may have beneficial actions on human standing balance following stroke (Lennon *et al.*, 2001); (Leung and Moseley, 2003). However, the effects of these devices on balance in relation to stroke are not well-established (section 1.8).

1.2.2 Gait

Normal human walking is defined as "locomotion involving the use of the two legs, alternately, to provide both support and propulsion" (Whittle, 1998). Locomotion is the process of moving from one place to another. Gait is the means of achieving locomotive actions in relation to the nature of the task. Walking differs from running in that it involves continuous contact of at least one foot with the ground (Winter, 1991a; Winter, 1991b).

The major requirements for successful gait are: the production of a basic locomotor rhythm, support and propulsion of the body in the intended direction, dynamic balance control of the moving body, and the ability to adapt the movement to changing environmental demands and goals (Inglin and Woollacott, 1988). In this thesis, the terms gait/walking and ambulation/locomotion are used interchangeably. Gait is a cyclic process. A normal 'gait cycle' is shown diagrammatically in Figure 1.1. The gait cycle starts when, for example, the right heel touches the ground and ends when the heel of the same extremity makes re-contact with the ground. The gait cycle includes two phases, stance and swing. The stance phase, which constitutes 58 - 61 % of the normal gait cycle, is the interval in which the foot of the reference extremity is in contact with the ground (Whittle, 1998). The swing phase (42 - 39 % of the cycle) is that portion in which the reference extremity does not contact the ground. Stance percentages increase at slower walking velocities (Bohannon, 1997). During walking, the centre of gravity transfers outside the base support of the feet thereby creating a continuous state of imbalance. Placing the swinging foot ahead of and lateral to the centre of gravity prevents falling (Whittle, 1998).

With healthy subjects, heel-strike (also called initial contact) occurs when the heel makes initial contact with ground. The foot-flat (loading response) phase starts immediately after heel-strike, when the foot fully contacts the ground. Mid stance begins when the centre of gravity passes directly over the weight-bearing lower extremity. Heel-off and toe-off (terminal stance or push-off) occur when the heel and toe leave the ground. The period between heel-off and toe-off is also known as pre swing. The swing phase starts as the toe of one extremity leaves the ground, and ends prior to the heel-strike of the same leg. Acceleration begins (initial swing) when the toe leaves the ground and ends when the respective leg is directly under the body (mid swing); deceleration occurs after the knee extends preparing itself for heel-strike (terminal swing) (Dannenbaum, 1982; Whittle, 1998).

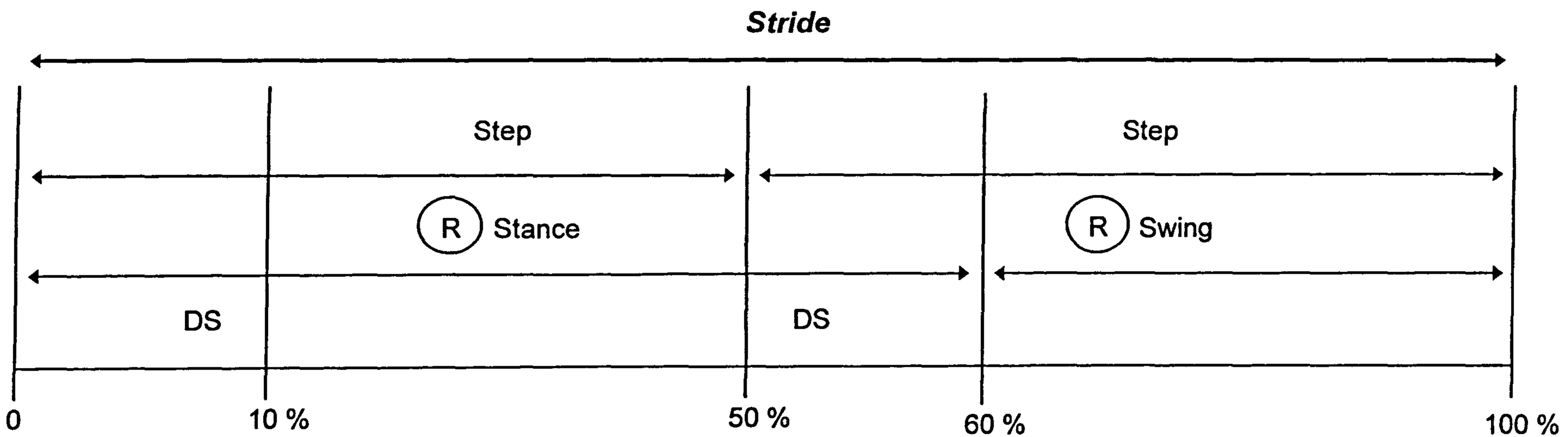


Figure 1.1 Gait cycle as a single stride presented from the right leg heel strike to same leg floor re-contact. DS = double support.

1.2.2.1 Gait adaptation and ageing

Gait velocity is maintained through adult life until the seventh decade; thereafter, gait velocity usually declines by 12-16 % per decade and maximal velocity declines by about 20 % per decade. Older people have a reduced stride length, spending more time with both feet on the ground (double support), and less time with one foot on the ground (single support). Stance time (the proportion of gait cycle with the foot on the ground) increases in men from 59 % in 20 year olds, to 63 % in 70 year olds, which increases double support time from 18 % to 26 %. Kinematic changes have also been described associated with a shorter step length, including reduced pelvic rotation, hip flexion/extension and ankle plantar flexion (Judge *et al.*, 1996).

Several early physiological studies lead to proposals for the existence of a gait adaptation process in the elderly population, which was explained by a general decrease in muscle strength due to loss of motor neurons, muscle fibres and aerobic capacity (Lee and Lishman, 1976; Carr and Shepherd, 1998a). Studies by Bohannon (1997) have confirmed that gait speed is reduced typically in elderly people with lower extremity muscle strength. Elderly people adapt their gait in a variety of ways in order to meet the specific weakness. For example, the elderly tend to 'drop' their pelvis into an anterior-tilt during stance phase to compensate for weak hip extensors. Such posture also leads to hip flexion contracture (Baer and Smith, 2001).

Muscle contraction promotes aerobic respiration, which can be monitored experimentally by measuring the amount of oxygen used by the muscle during a given task (Sulch *et al.*, 2002). Standard tables for energy consumption during walking for a wide range of ages and gait velocities indicate that during walking at normal velocity, the elderly consume significantly more oxygen for a given distance than the young, even though the elderly group walk significantly slower that the young. Stride length averages 1.5 m in younger subjects. Older adults display a shorter stride by increasing their

cadence (step/min) to a greater extent than younger adults. Thus, the decreased stride length most likely reflects instability or muscle weakness during single limb support of the opposite leg. People over 80 years of age have a 20% increase in both step width and double support time compared to people between 20 and 25 years old (Prince *et al.*, 1997; Baer and Smith, 2001).

1.2.2.2 Gait impairment following stroke

Gait problems in patients with stroke are complex and include both neurophysiological and biomechanical factors. The most significant impairments in gait performance immediately following a stroke are diminished strength and inability to generate voluntary muscle contractions of normal magnitude in any muscle group (Bonita and Beaglehole, 1991). Inappropriate timing or grading of muscle activity is also likely to occur (Wooley, 2001; Leung and Moseley, 2003). Later, there may be further impairments, including spasticity and changes in the mechanical properties of muscle leading to abnormal extensibility of muscle groups that serve the hemiplegic side (Bonita and Beaglehole, 1991; Dietz, 1992). It is well established that most stroke survivors have continuing problems with gait (Chin *et al.*, 1982; Wade *et al.*, 1987; Jorgensen *et al.*, 1995) and without appropriate rehabilitation, optimal functional recovery is rarely achieved (Bach-y-Rita, 1990; Kwakkel *et al.*, 1999; Baer and Smith, 2001). Further details of the primary effects of stroke on gait (muscle weakness, joint immobility, spasticity, sensory deficits, and motor dysfunction) are described below.

i) Muscle strength

Gait performance has been largely correlated with the strength of the more involved lower limb muscles in stroke. Muscle activity following stroke has been studied using a variety of methods. For example, electromyography (EMG) was established as a useful technique following the identification of decreased muscle activity on the paretic side (Hirschberg and Nathanson, 1952; Wooley, 2001). The Manual Muscle Test

(Demeurisse *et al.*, 1980) is a system based on a graded scale from 0-5, which identifies gait deviation post-stroke when muscle strength grades of less than 4 are achieved (Demeurisse *et al.*, 1980). Further muscle test methods include the dynamometer, which has been used effectively in muscle activity evaluation in gait analysis following stroke (Nadeau *et al.*, 1999b).

Post-stroke, quadriceps and hamstring muscle activity has been shown to be prolonged at the end of the stance phase, and inadequate strength of the dorsiflexor muscle group results in the foot dropping passively into plantar flexion (Knutsson and Richards, 1979). If the weakness is mild, a heel strike still occurs, but there is inadequate strength to control the loading response. Consequently, the foot 'slaps' to the floor. Greater weakness deprives the patient of a heel strike and initial contact is made with a flat foot (Knutsson and Richards, 1979). These authors also described two other types of aberrant muscle activity specific to stroke walkers. One involves hyperactive stretch reflexes, which leads to premature activation of the calf muscles in early and mid stance phase which precludes the accomplishment of effective push-off by the plantarflexors. In this group, the ability to generate sufficient muscle force for stability is diminished. The other type of disorder involves excessive and stereotyped co-activation of several muscles groups, which disrupts the normal sequence of motor events. Thus, numerous muscle groups of stroke patients were found to co-activate abnormally during late swing or stance phase (Knutsson and Richards, 1979). Current knowledge based on a study of subjects (15 stroke patients, 12 healthy) walking on a treadmill, using footswitches and EMG analysis techniques, questioned whether abnormal function of the tibialis anterior muscle is the only factor leading to a dropped-foot, and it was hypothesized that inappropriate calf muscles activity may also contribute to the problem during heel-strike (Burridge *et al.*, 2001).

The gastrocnemius activity of stroke patients has been reported to peak during the initial contact of the foot with the ground, and then to change rapidly to low and uniform

levels during the mid- and late-stance phases of the gait cycle, whilst premature activation of the soleus results in the quadriceps working harder to restrain the rate of knee flexion (Hirschberg and Nathanson, 1952; Wooley, 2001). The strength of the quadriceps, hip extensors, and soleus are therefore the major determinants of an individual's weight acceptance capability. Hyperextension of the knee adds to its weight bearing stability and presents the most common substitution for quadriceps insufficiency (Shiavi *et al.*, 1987b; Knutsson and Richards, 1979). Consistent dysphasic activity is evident in the rectus femoris during stance and swing phases (Pinzur *et al.*, 1987).

The level of activity needed to rest on the heel lever during the loading response is greater (grade 4 with Manual Muscle Test) than used to support the foot in swing (grade muscle 3). Inadequate dorsiflexion (< grade 3 with Manual Muscle Test) is critical during mid-swing, as this requires increased hip and knee flexion to avoid the toe dragging on the ground (Dannenbaum, 1982; Olney *et al.*, 1994; Lamontagne *et al.*, 2002). Consequently, all of the events that characterise mid-swing become disrupted (Demeurisse *et al.*, 1980; Winter, 1991b). Circumduction and 'hip hiking' are alternate means of accommodating a passive drop foot when hip flexor muscles cannot meet the increased demand (Burdett *et al.*, 1988). Nadeau *et al.* (1999b) identified different types of muscle activity when stroke subjects used the ankle plantarflexor muscles (calf muscles) at maximal activity to minimise plantarflexion motion during late stance phase, and as noted, as simultaneous compensation for this, stronger hip flexors contraction in the early swing phase.

Characteristics of the stance phase of hemiplegic gait include an equinovarus foot position that results in forefoot or flatfoot strikes during loading. Hyperextension of the knee in mid-stance is typical, with a forward lean of the trunk (Lamontagne *et al.*, 2002). Difficulty when placing the hemiparetic leg in a trailing position during terminal stance allows the body weight to advance over the forefoot with a subsequent heel-rise. Often, the pelvis is retracted on the stance leg on the unaffected side, whereas the affected

side drops due to abductor weakness. Forefoot toe-off (push-off) is low or missing due to the muscle weakness, or reflective hyperactivity of the calf muscles in the pre-swing phase (Lamontagne *et al.*, 2002). Common problems experienced during the swing phase include toe-drag, which impedes progression due to inadequate dorsiflexion, tibialis anterior paresis (Winter, 1991b; Richards *et al.*, 1993), and inappropriate foot placement, which is the result of incomplete knee extension and ankle dorsiflexion at the end of swing (Montgomery, 1987). These changes are reflected in a loss of functional mobility (Potter *et al.*, 1995). Muscle weakness on the side most affected by stroke has been shown to increase overall activity on the unaffected side, which may exert a compensatory influence (Shiavi *et al.*, 1987b; Nadeau *et al.*, 1999b; Kirker *et al.*, 2000; Lamontagne *et al.*, 2002). The rate of recovery of muscle activity impairment after stroke is greatest in the first few weeks and then slows after 2 to 3 months, although improvements have been identified up to two years after the initial insult (Turton *et al.*, 1996; Kirker *et al.*, 2000).

ii) Joint immobility

Stroke often results in loss of joint mobility and the development of joint contractures. The quadriceps' force required to stabilise a flexed knee is proportional to the load on the femoral head and the angle of knee flexion (Olney *et al.*, 1994). For each degree of flexion, the force required increases, on average, by 6 % of the load on the femoral head. In a 5-degree position, the quadriceps force is 30 % of body weight, whilst in a 30-degree position; the force increases to 210 % of body weight. Patients with adequate hip extensor and ankle plantar flexion muscle function can decrease the quadriceps force by locking the hip joint and leaning forward. By this means, the body weight is anterior to the knee and the stress on the knee joint and requirement for quadriceps force is reduced. However, the muscle work used to stabilise the hip and ankle is greater. Thus, stroke patients often cannot make such substitution (De Quervain *et al.*, 1996).

Stroke-mediated plantarflexion contracture interferes with normal tibial advancement during stance phase. Thus, a foot flat posture persists with the tibia locked in a backward angle due to ankle immobility (Evans *et al.*, 1997). To advance over the limb, affected individuals rely on the level of accommodation available at their knee and hip. Knee hyperextension can move the body forward when the tibia advances insufficiently, the extent of which is determined by the natural range of the patient (Burdett *et al.*, 1988). Patients who do not have an adequate range turn to hip flexion to move their body weight forward. However, this increases the demands on the hip and back extensor muscles (Dannenbaum, 1982).

iii) Spasticity

Spasticity is typified by hypertonicity, hyperreflexia and clonus, and is caused by pyramidal and extrapyramidal insult. In spasticity due to cerebral insult, tone is primarily in the antigravity muscles (extensor muscles) (Lamontagne *et al.*, 1997). In spinal spasticity, flexor muscle spasticity is often apparent. Both of these types of spasticity have been implicated in the occurrence of abnormal gait pattern characteristics in stroke patients (Knutsson and Richards, 1979; Shiavi *et al.*, 1987a).

Premature activation of stroke patients' ankle plantar flexor muscles (calf muscles) during stance phase is often accompanied by knee hyperextension and the patient may walk with a stiff leg. When dorsiflexion is present, it usually manifests as overactive anterior tibialis muscles producing doriflexion with excessive inversion (Knutsson and Richards, 1979; Shiavi *et al.*, 1987b). In some patients, the clonic activation bursts in early and midstance phases interfere with the plantar flexor lengthening contraction and dorsiflexion movement at the ankle, resulting in knee hyperextension (Knutsson and Richards, 1979). Lamontagne *et al.* (2001) demonstrated an abnormal muscle response (spasticity) in the gastrocnemius muscles during stance phase, on the affected side, but not on the unaffected side. These researchers also identified reduced dorsiflexion during the pre-swing phase, which apparently was unrelated to the hyperreflexia and

accounted for by muscle weakness. However, it is likely that hyperactive muscles in the lengthening period of the plantarflexors in early stance phase perturbs the lower limbs' joints movements and compromises the efficiency of ankle push-off in late stance phase (Lamontagne *et al.*, 2001).

An individual with stroke has difficulty transferring body weight over the affected limb secondary to excessive plantarflexion. Quadriceps spasticity interferes with knee flexion movement during the pre-swing, which halts forward transference of the body weight. Patients usually shorten the step on the unaffected side and decrease single limb support phase on the affected side (Department of Health, 2001; Mauritz, 2002).

iv) Sensory loss

Loss of tactile and proprioceptive function following a stroke results in wide, irregular and uneven steps. Dysfunctional vestibular operation leads to unsteadiness during walking and for example an inability to descend stairs without support. When moving, inanimate objects often appear uneven, indicating that the vestibular system is unable to support proper ocular fixation during body motion (Patla, 1996).

Pain and temperature sensation of stroke patients may also be impaired. However, the most frequent problems are evident in the discrimination and interpretation of information regarding movement, including perception of muscle force, texture and stereognosis (Knutsson and Richards, 1979). The effects of poor feedback from regions such as the foot can lead to, for example, collapse of the leg when stepping off a kerb and experience of such a problem can easily result in the loss of an affected subjects' confidence (Carr and Shepherd, 1998b).

v) Motor dysfunction

Biomechanical studies of gait kinematics, kinetics and muscle activation have been used to evaluate motor dysfunction in individuals after stroke. However, compared with

the large body of data-based studies of gait in healthy subjects, there are at present only a limited number of reports on walking performance of stroke patients. Earlier studies have concentrated mainly on temporal variables, and only recently has work focused on joint angle excursion, kinetics and mechanical power for clinical purposes. The ability to conduct these latter experiments coincides with the availability and ease of-use of modern computer technology (Wooley, 2001).

One consistently reported difference between able-bodies subjects and individuals following stroke is in gait velocity (Lehmann *et al.*, 1987; Jones and Barker, 1996; Kwakkel and Wagenaar, 2002). Subjects with hemiplegia and significantly reduced gait velocity typically exhibit decreased stride length, shorter stance phase and longer swing phase on the affected leg. In order to compensate for these changes, the stance/swing ratio for the unaffected leg shifts to an increased stance and decreased swing phase (von Schroeder *et al.*, 1995; Evans *et al.*, 1997; Carr and Shepherd, 1998b).

Biomechanical gait analyses of spatial (distance) and temporal (timing) factors have shown that stroke patients walk at less than half the speed of healthy adults, averaging 0.62 m/s (37 m/min), compared with 1.36 m/s (82 m/min) for healthy adults (Turnbull *et al.*, 1995; Witte and Carlsson, 1997). However, walking speed is critically dependent on the degree of recovery following stroke (Wade and Hewer, 1987; Potter *et al.*, 1995; De Quervain *et al.*, 1996) and walking independence and distance (Bohannon *et al.*, 1989; Friedman, 1990; Wagenaar and Beek, 1992). The distance over which gait ability has been studied varies considerably, with reports of analyses undertaken between 2-30 metres (Friedman, 1990; Roth *et al.*, 1997; Witte and Carlsson, 1997). Standardised 10-meter tests are the most favoured approach, for practical and safety reasons, although this distance is probably not representative for the entire community.

Although most clinical studies of walking in patients following stroke have examined temporal measures, some have monitored joint angle excursions, kinetics and mechanical power. In general, these studies have shown that joint angular

displacements are decreased (Lehmann *et al.*, 1987; Burdett *et al.*, 1988) with evidence of reduced ankle dorsiflexion at initial foot contact (Dettmann *et al.*, 1987; Patla *et al.*, 1990), and decreased knee flexion in swing and lack of knee flexion in stance phases (Lamontagne *et al.*, 2002). In terms of decreased amplitude of hip extension in stance associated with decreased velocity, De Quervain *et al.* (1996) reported that the pattern of motion of the lower extremity on the affected side had a stronger association with the clinical severity of muscle weakness than with the degree of spasticity. The authors also noted a delay in the initiation of flexion of the hip during the pre-swing phase, whilst flexion of the hip and knee and dorsiflexion of the ankle progressed only slightly during the swing phase (Lamontagne *et al.*, 2002). During the stance phase, there was decreased muscle effort and a coupling between flexion of the knee and dorsiflexion of the ankle. The duration of pre-swing was most prolonged for the patients who had the slowest gait velocities. The ankle, knee and hip power were reported to be abnormal during the increased stance phase with reduced swing phase ankle plantarfexion on the affected side of stroke patients (Olney *et al.*, 1994; Wooley, 2001).

Generally, for most disabled people who have had a stroke, joint angular displacements are decreased. Thus, there are reports of decreased ankle dorsiflexion at initial foot contact (Lehmann *et al.*, 1987), lack of knee flexion during stance phase (Dettmann *et al.*, 1987) and reduced ankle and knee flexion in swing phase (Patla *et al.*, 1990; Olney *et al.*, 1991; Olney *et al.*, 1994; Lamontagne *et al.*, 2002). It was also reported that stroke patients possessed significantly less hip extension at mid-stance and push-off phases than healthy subjects (Lehmann *et al.*, 1987; Olney and Richards, 1996). De Quervain *et al.* (1996) described a delay in initiation of flexion of the hip during pre-swing phase, and flexion of the hip and knee, and dorsiflexion of the ankle, which progressed only slightly during swing phase causing toe-drag. These authors also noted that the duration of pre-swing was extended in the subjects who had the slowest gait velocities.

Abnormal co-activation of leg muscles appears to be a characteristic of stroke patients' gait that is thought to alter the biomechanical characteristics of the limbs and their capacity for absorbing and storing energy (Blaszczyk *et al.*, 2000). Excessive coactivation of antagonist muscles, which results in lower moments, may also decrease plantarflexior force production during gait (Winter, 1991b). Lamontagne *et al.* (2002) found that the swing phase reduced plantarflexion moment was associated with increased plantarflexion passive stiffness. The muscle power patterns at the three lower limb joints of stroke subjects (affected side) have a similar to normal shape with reduced amplitude (Evans *et al.*, 1997), and the energy expenditure of walking was reported to be higher for stroke subjects than for able-bodied subjects (Hansen *et al.*, 1988).

Increased gait velocity is indicative of improved performance. Many studies support the view that gait velocity reflects both functional and physiological changes in individuals following stroke (Olney and Richards, 1996; 2001; Baer and Smith, 2001). With an increase in velocity, Olney *et al.*, (1997) reported a tendency towards greater hip extension at the end of stance and increased work by the hip flexors at the initiation of swing, which are both critical components of an effective gait pattern. In a subsequent study, a strong relationship was found between the gait velocity and the maximum hip flexion moment (Olney *et al.*, 1994). Bohannon (Bohannon *et al.*, 1989; Bohannon *et al.*, 1991) also reported a positive relationship between the velocity of walking and the strength of the affected lower limb in stroke patients.

1.3 Disability: definition and classification

The principal system used to categorize disability is the International Classification of Impairment, Disabilities and Handicap (ICIDH) devised by the WHO (WHO, 1980). This system incorporates the concepts of disease, impairment, disability and handicap as a framework for the study of disability. In this context, disease represents changes that occur at the organ level (e.g. infection, inflammation, bone fractures), and changes in

body structure and function. Impairment includes loss or abnormality of anatomical, physiological, mental or emotional capacity. By definition, disease leads to impairment because it causes physical damage that leads to pathology, which interferes with the anatomy or the normal physiology. Impairment however, may exist in the absence of pathology, for example, when it is due to a congenital deformation. Disability occurs at the personal level and is a restriction in or lack of ability to perform common activities in the manner, or within predefined limits, deemed 'normal'. According to the ICIDH system, the inability to transfer between surfaces, ambulate, or climb stairs qualifies as a disability. Furthermore, any limitations in movements that result from impairments are categorized as a disability. The impact of a handicap registers on the social rather than the personal scale. Thus, a social limitation is placed on a person who is physically unable to navigate the environment without assistive devices (Lin and Woollacott, 2002).

Recently, a more comprehensive and revised version of the ICIDH has been published (WHO, 2001). This is known as the International Classification of Functioning, Disability and Health, or ICF. Key features of this document, which incorporates developments from the intervening two decades of disability-related research, are the assignment of functional and structural domains to body systems in relation to the impact of different health states on activity and participation within society. The ICF also replaces earlier definitions of disability and handicap with the concepts of 'capacity' and 'performance', and applies these constructs to a single list of activity and participation domains (task or action). Capacity refers to an individual's ability to execute a task or action in a uniform environment, assuming motivation to perform the task, e.g. ability to walk 100 metres on a level, well-illuminated, and non-slippery surface. Performance describes how an individual performs an action within their current environment. The difference between current capacity and performance reflects the impact of the actual environment (and

possibly motivation) relative to the uniform environment. It is possible to measure an individual's performance and capacity, both with and without personal aids.

1.4 Orthotic intervention

It is well known that mobilization can improve physical recovery, reduce the likelihood of a further stroke and increase the level of capacity in our daily life. Therefore, restoration of mobility is crucial for independent living and balance and gait training are an essential part of neurological rehabilitation. The use of ankle-foot orthoses as supportive devices for standing balance and gait deficit has been a component of rehabilitation since 1950. However, early orthoses were most often designed for specific diseases without taking into consideration the individual requirements of the patient (Montgomery and Inaba, 1969; Perry, 1969; de Vries, 1991; Aisen, 1992). Although designs of orthoses have since been introduced which do take into account specific patient requirements, the use of orthoses in neurological rehabilitation is often restricted or ignored, and non-assistive device therapies are, in general, the preferred approach (Bobath, 1990; Carr and Shepherd, 1998b; Davidson and Waters, 2000; Lennon *et al.*, 2001; Lennon, 2001).

Although the molecular and cellular bases of the recovery processes described earlier are, at present, poorly understood, nowadays there is better knowledge of the relationships between neural and biomechanical mechanisms underlying the acquisition of motor skills (Dietz, 1992; Bowker, 1993; Leonard, 1995). There is also renewed interest in theories proposed to explain how brain reorganisation might be promoted or modified post-stroke via orthotic intervention. Progress in these areas, together with novel developments in materials science, have important implications for the clinical application of orthoses in stroke rehabilitation (Chu, 2001). Novel designs of orthoses are believed to encourage the therapeutic process of ambulation by neurophysiological and biomechanical actions (Hylton, 1990; Mueller *et al.*, 1991). These devices are the main focus of the original research described in this thesis.

1.4.1 Ankle-foot orthoses

Ankle-foot orthoses (AFOs) or below-knee casts have been recommended to lessen gait deviations and assist functional ability in patients with neurological deficits (Reding and McDowell, 1987; Condie and Condie, 1995). Early descriptions of these devices emphasised their role in the management of gait abnormalities primarily for patients with foot drop and ankle instability (Perry, 1969; Lehmann *et al.*, 1970) and designs were based entirely on biomechanical principles, with emphasis on force systems that act upon body systems for corrective, assistive, substitution and protective functions (Aisen, 1992). Ankle-foot orthoses primarily control motion around the ankle via a three-point force system achieved through contact of the calf section and the footbase of the orthosis with the limb (Lehmann, 1979; Lehmann *et al.*, 1987; Aisen, 1992; Bowker, 1993; Condie and Meadows, 1993). This three-point pressure system (which lies in the saggital plane) is designed to limit plantarflexion, which prevents foot slap at initial contact due to inadequate muscle control of ankle flexion and ensures clearance during swing. Depending on their planned function, ankle-foot orthoses may also incorporate one or more of the following three point force systems. Firstly, a three point that lies in the frontal plane and attempts to stabilise the subtalar joint, which in theory prevents calcaneal varus. Secondly a three-point pressure system which lies in the transverse plane and which blocks forefoot adduction and stabilises the midtarsal joint with assistance from the shoe. And finally a three-point pressure system which lies in the frontal and saggital planes and is designed to prevent the talus from translating anteriorly within the ankle ligament lock through circumferential containment. This pressure system directs one force posteriorly towards the calf, a second force towards the plantar surface of the foot and a third opposing force anteriorly towards the talus (Condie and Meadows, 1993).

Traditionally, AFOs have been constructed from metal and leather and attached to the patient's shoe (conventional AFOs). This type of orthosis may have double or single

uprights, with a calf band and possibly a springmechanism ankle joint. Such bracing apparently provides resistance that alleviates ankle varus (Aisen, 1992; Condie and Meadows, 1993) during initial contact and lessens spasticity and contracture, in addition to providing better knee stability when walking (Perry, 1969; Lehmann *et al.*, 1987). Lehmann *et al.* (1987) carried out a biomechanical assessment of the gait pattern of seven stroke subjects using two different types of conventional AFO (with 5° dorsiflexion and 5° plantarflexion stops). The results were compared with data recorded with the subjects wearing their own shoes. It was found that the AFO with a 5° dorsiflexion stop increased gait velocity and the knee flexion moment compared to the AFO with 5° plantarflexion stop and shoe. The authors also noted that this AFO provided increased heel strike duration, but the push-off phase was longer with the plantarflexion AFO. Both AFOs shortened the mid-stance phase compared to shoes. The authors suggested that the main goals of AFOs were to provide adequate medio-lateral stability during the heel-strike and stance phase and sufficient toe clearance during swing phase and to increase knee stability, in order to approximate a normal gait pattern whilst reducing energy expenditure (Lehmann *et al.*, 1987; Lehmann, 1993).

The Valens calliper is a conventional AFO constructed from a single rigid upright, with a dorsiflexion-assisted spring mechanism on the lateral and medial malleollae level, with a plantarflexion stop. Using this type of orthosis, Hesse *et al.* (1996) noted positive effects on several gait parameters when assessing 19 stroke subjects with an 'infotronic force' shoe system (which measures vertical force trajectory under the foot) and stopwatch. An increased gait velocity, stride length, and cadence were evident with the callipers compared to shoes alone and barefoot. The authors also reported an increase in the gait line, which was apparent for both the affected and unaffected foot. No changes were identified in stance and swing symmetries or double stance duration. However, more recent work reported by this research group (Hesse *et al.*, 1999) using the same splints failed to identify any changes in gait velocity, stride length or cadence. Instead,

this later work revealed that subjects' relative single-stance time and terminal double support duration was increased with use of the orthosis. In addition, swing symmetry was improved and the gait line of the affected leg was increased; greater dorsiflexion during stance phase and less plantar-flexion during swing phase were also noted (Hesse *et al.*, 1999).

With the development of high temperature plastics, orthotists have recently fabricated more lightweight and cosmetic ankle-foot orthoses. The first thermoplastic models (the most commonly used material is polypropylene) introduced in the late 1960s were of rigid design and were fitted inside the shoe (Sarno and Lehneis, 1971). Polypropylene AFOs are also available in a wide variety of designs, offering many choices of mechanical features to suit an individual's requirements. This is achieved by varying material thickness, alterations in the ankle trim-line and adjustment of the angle at the ankle region of the device (Lehmann, 1993; Condie and Meadows, 1993). Using a cross-over experimental design, Mojica *et al.* (1988) assessed eight stroke patients walking with and without a plastic AFO. This study identified beneficial effects with an increased maximum gait velocity, stride length, and cadence when using AFOs. In addition, the use of the orthoses reduced the lateral sway of the centre of foot pressure, and decreased body sway of standing balance. In a single case study, Butler *et al.* (1997) compared the effects of a plastic AFO with barefoot walking on a hemiplegic subject with traumatic head injury. Positive effects of the AFO were described, with reduced knee pain, a 67% reduction in the maximum extending moment of the affected knee at 1 year, a 42% reduction of early heel lift on the left at 1 year, together with an increase in single standing balance on the affected leg.

The effects of polypropylene AFOs have also been compared with other therapy methods. For example, Beckerman *et al.* (1996) measured the efficacy of an AFO with a 5° dorsiflexion stop and tibialis nerve blocking on the gait of stroke subjects. In this study, sixty subjects were allocated to four experimental and placebo groups. The

outcome measures were gait velocity measured using an infra-red beam watch, and overall walking ability measured by a self-assessment scale known as the 'Sickness Impact Profile (SIP). The main outcome of this study was that there were no beneficial effects of the AFO on stroke subjects' walking ability (Beckerman *et al.*, 1996).

A very different type of AFO, called an air cast AFO (or air stirrup brace), has also used in the rehabilitation of the stroke patient, and has been recommended as a temporary measure during the early stages of stroke rehabilitation (Burdett *et al.*, 1988). This prefabricated device consists of inflatable air cells positioned on both sides of the malleolus and extending midway up the lower leg, and is used mainly for patients who require only minimal support for ankle medio-lateral instability (Hayes, 1983; Burdett *et al.*, 1988). Burdett *et al.* (1988) reported findings of studies that compared the effects of this type of orthosis with those of a polypropylene AFO and a conventional AFO on several spatio-temporal and joint kinematics variables of 19 stroke subjects. Use of the air stirrup brace was more effective in reducing the foot inversion at the heel strike and afforded less angular changes in joint motions than either the polypropylene AFO or conventional AFO. The conventional AFO provided less plantarflexion at heel strike, whereas both braces reduced plantarflexion during the swing phase. No changes in joint motion of the ankle, knee and hip were evident under the three bracing conditions. In addition, the study discerned no effects of the devices on gait velocity, stride length, stride time, or the base of support (Burdett *et al.*, 1988).

The development of polypropylene AFOs continued actively and later devices have been manufactured to many designs, which may be broadly classified as either rigid or flexible (articulated AFO), depending on whether they are designed to permit or restrict flexion of the ankle (Toller *et al.*, 1989; Aisen, 1992). The articulated AFO (sometimes referred to as a hinged AFO) is constructed using polypropylene and incorporates an ankle joint (metal) situated close to the malleolus. This design aims to block ankle plantarflexion, whilst permitting free ankle dorsiflexion during the gait cycle.

In a study of the articulated AFO in stroke subjects carried out by Tyson *et al.* (1998) four subjects were tested using the splint and without it. The results indicated an increased gait velocity and lengthened strides and steps when using the orhtosis. In addition, some improvement was seen in gait symmetry. These positive findings supported the subjects' positive opinion of orthses, although half of them felt that this splint did not look good. In a more recent and comprehensive study, Tyson and Thornton (2001) assessed the effects of an articulated AFO on 25 stroke subjects using a with/without experimental design. The study involved objective gait evaluation of spatio-temporal variables monitored when subjects walked on a paper walkway, with ink-soaked stickers located at the apex of their heels. Subjects' opinions on the effects of orthosis were ascertained via face-to-face questionnaire. It was concluded that the articulated AFOs improved gait velocity, stride length and cadence and that, overall, there was an improvement in functional ability. Subjects' own opinions indicated that the orthoses was comfortable and easy to put on; they also expressed reservations about the appearance of the device, but overall felt that the benefits outweighed this factor.

So-called 'anterior' AFOs, which have been used and tested primarily in far eastern countries, are constructed with polypropylene material that supports the ankle more firmly on the anterior side of the lower leg and foot. Wong *et al.* (1992) assessed the anterior AFO with 5°-10° dorsiflexion stops in comparison to a conventional polypropylene AFO model (with support provided at the ankle, over the back of the lower leg, and under the foot). For the six chronic stroke patients studied, no differences in gait or balance parameters were evident between the two devices.

In another study, Chen *et al.* (1999) described the effects of an anterior AFO on 24 long-term stroke patients' static and dynamic standing balance. Using a crossover study, with and without AFOs, standing balance was assessed via a force platform. The study revealed positive effects of the AFO on lateral weight shifting and weight bearing on the affected leg, when subjects' weight was shifted to that side. It was apparent that

postural sway and symmetry and anterior-posterior weight shifting abilities were unaffected by the orthosis.

Very recently, Teasell *et al.* (2001) have assessed the functional details of AFO users and non-users (type of AFO was not specified), retrospectively following their discharge from hospital. This work indicated that 93 patients from 423 (22%), who were discharged with an AFO over a 20 year period, were associated with a significantly lower admission and discharge scores of disability (FIM instrument). In addition, motor recovery (the Chedoke-McMaster, Stroke Impairment Inventory), and balance function (Berg Balance Scale) tests provided lower scores for the AFOs users compared to those without the orthoses.

As indicated earlier, alignment variations at one segment of the body during gait can alter the movement patterns throughout the entire lower limb and trunk of stroke subjects (section 1.6.5). One of the goals of orthotic prescription should be to address this relationship between body segments. This objective represents a departure from a more traditional approach to orthotic prescription that focuses on a specific single-joint problem, and places less emphasis on the ramifications of this treatment for whole-body upright function while moving (Hylton, 1990; Mueller *et al.*, 1991).

It is clear from the descriptions above that several aspects of balance and gait have been tested in relation to AFO use and stroke patients, and some of this work has provided encouraging findings. However, most of this research has been limited to prospective single-case studies, or small group studies (cross-over designs/ within-subjects designs). Thus, the precise mechanism of action and suitability of these devices for stroke patient rehabilitation is essentially uncharacterised.

1.4.2 Dynamic Ankle-Foot Orthoses

The development of orthotic design continues and, recently, a new concept has been developed based on a modified AFO. These novel devices are known as Dynamic

Ankle-Foot Orthoses (DAFO). The DAFO is a low, supra-malleolar splint, trimmed above the malleoli (Figure 1.2), which supports foot alignment and ankle supination-pronation whilst providing minimal restriction to ankle joint flexion-extension. The original research reported in this thesis concerns studies that aimed to determine if DAFOs can improve patients' balance and gait, and whether the use of these devices contributes to ambulatory and functional improvement during the early recovery period following stroke.

Although DAFOs are supportive, their design incorporates sufficient flexibility to facilitate tri-planar movement about the ankle and subtalar joint, making them suitable as an adjunct to the development of movement control (Hylton, 1990). DAFOs are constructed in a similar way to rigid AFOs, using thermoplastic materials, but the polypropylene used in their construction is very thin, allowing greater flexibility than traditional AFOs. The splint also optimises subtalar joint alignment through its supramalleolar design. It is trimmed anteriorly and posteriorly to allow maximal ankle motion in dorsiflexion and plantarflexion. Its design also differs from that of a rigid AFO in that a DAFO incorporates a functional, custom-molded insole, which precisely follows the patient'sdynamic arches (medial, lateral and anterior) under the foot (Figure 1.3). Theoretically, this insole design exerts neurophysiological actions via biomechanical constraints on the wearer's locomotor capacity. The toes are supported in the horizontal position to facilitate metatarsal alignment, and a 'cup' supports the heel and provides support to the subtalar joint. The metatarsal head area is deepened to support the forefoot in a neutral position. When a metatarsal head is positioned 3 - 5 mm lower than its proximal region, the forefoot is abducted and the subtalar joint is pronated, to enhance an improved dynamic balance response in single limb support. Similarly, the neutral position helps to provide optimal foot function and reproduce normal biomechanical function during ambulation (McPoil and Hunt, 1995).

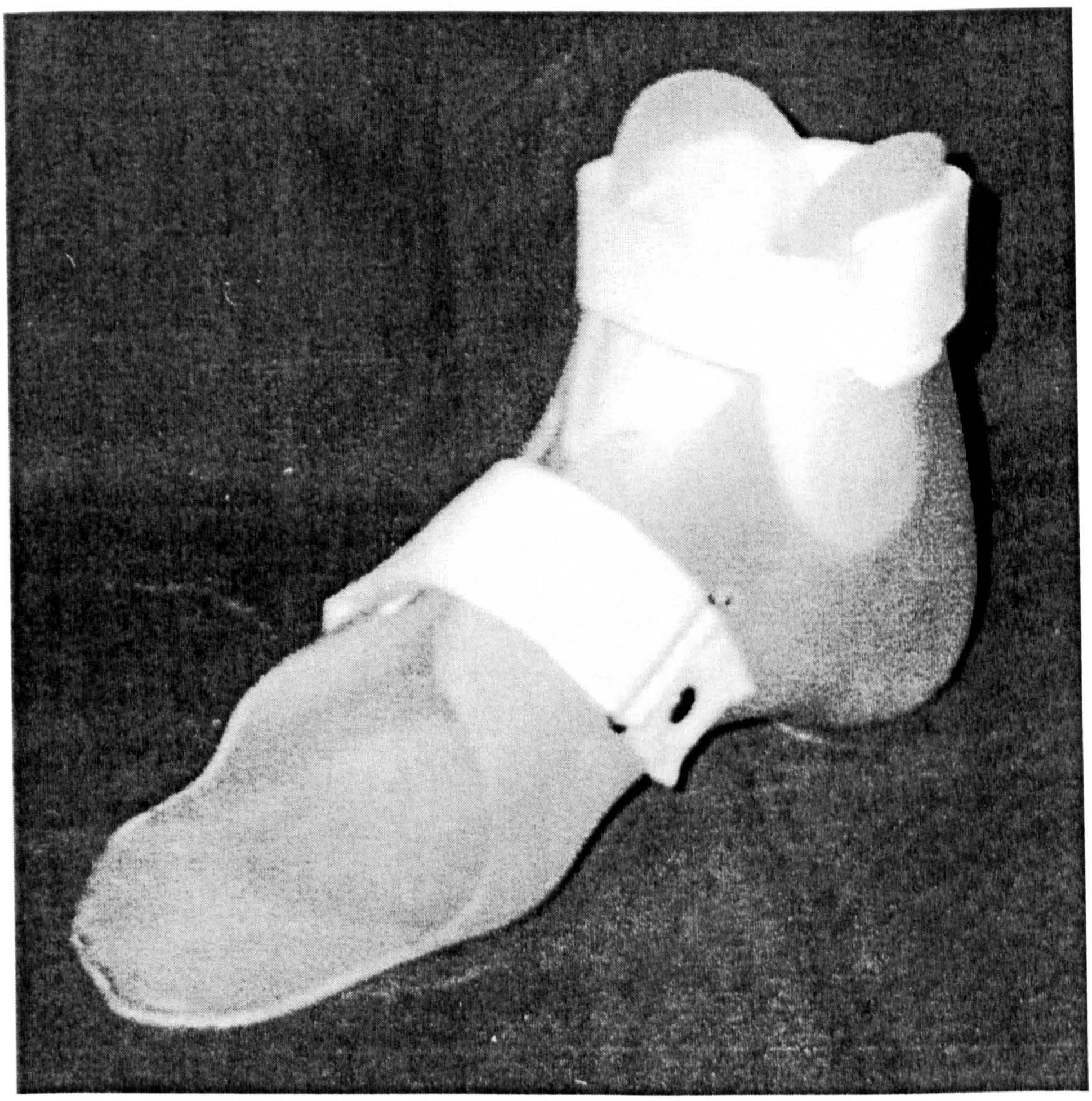


Figure 1.2 Dynamic Ankle-Foot orthoses design

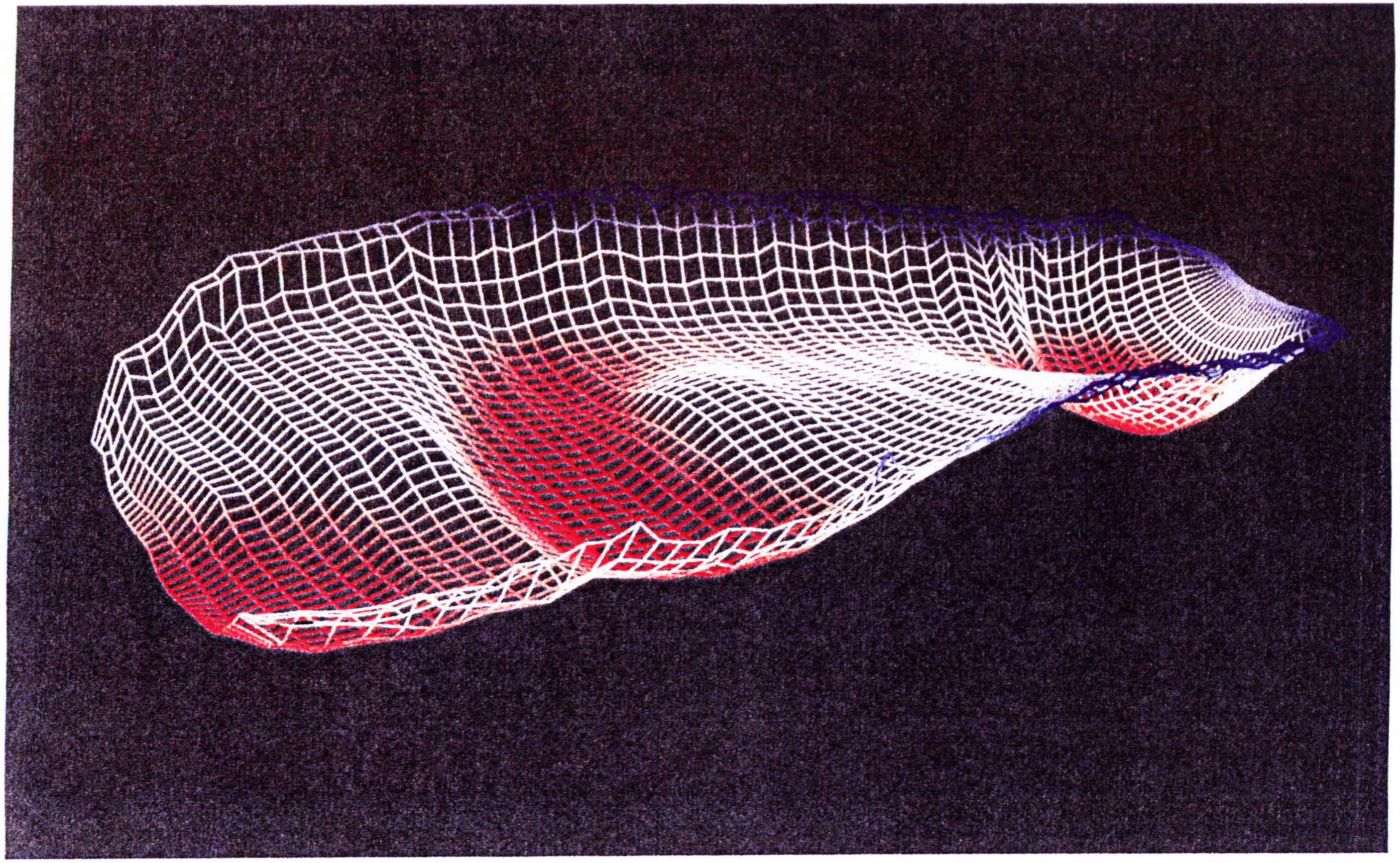


Figure 1.3 Computer visualization of insole used in a DAFO

1.4.2.1 Biomechanical and neurophysiological principles of DAFOs

To reiterate, in order to enable upright standing and walking, the body requires continuous sensory information from the vestibular apparatus and the visual and proprioceptive systems (including exteroreceptors in the sole of the foot). This information is relayed to the CNS, where processing occurs to determine the spatial position of the body (sections 1.4.1 and 1.4.2). Efferent adjustments are constantly made to modify muscle activity to maintain the body's dynamic equilibrium (Bach-y-Rita, 1981; Cohen, 1999). In stroke patients, both the pathways involved in the interpretation of sensory information and motor controls are often disturbed (Shumway-Cook and Woollacott, 1995). Rehabilitation with DAFOs may improve both impaired mechanisms. Thus, a fundamental principle of DAFOs is that their design uses biomechanical principles to modify the forces and movements at the position of, and therefore the ankle-foot complex, and thus to modify the effects of external forces on more proximal joints (Bowker, 1993), and neurophysiological facilitation and inhibition through somato-sensory tracts.

It is postulated that DAFOs support the forefoot and subtalar joints in their neutral alignments and give total under-foot contact to permit more consistent foot positioning, thus assisting improved dynamic control throughout the joints of the lower limb and trunk (Harris and Riffle, 1986; Rosamond *et al.*, 1999). Furthermore, during active movement, the orthosis may permit neurophysiological facilitation/inhibition by the use of proprioceptive feedback, through the neutral joint position (Hylton, 1990), and tactile information via cutaneous contact (Feuerbach *et al.*, 1994). Both of these factors may stimulate normal muscle activity and gait pattern. DAFOs endeavour to achieve these effects by individual orthotic design, material selection and precise biomechanical adjustment.

1.4.2.2 The use of DAFOs with adult neurological patients

Clinical studies of DAFOs were carried out predominantly in the USA during the early 1980s for children with cerebral palsy (Cusick and Sussman, 1982; Duncan and Mott, 1983). Positive clinical observations from these studies have prompted experimental evaluation of the orthoses (Harris and Riffle, 1986; Hinderer *et al.*, 1988; Overby *et al.*, 1991; Curtis, 1995; Kuoppamaki-Herzig and Kalbe, 1995; Crenshaw *et al.*, 2000; Romkes and Brunner, 2002).

Over past the ten years, the effect of DAFOs on the gait of stroke patients has been examined using single-case studies. Diamond and Ottenbacher (1990) assessed a thirty-two-year-old stroke patient who had suffered a right side hemiparesis ten months prior to the study. Stride characteristics of gait were assessed under three conditions; barefoot, using a polypropylene AFO, and using a DAFO. These conditions were randomised during twelve measurement sessions over a period of one month. It was observed that the subject showed significant improvements in walking velocity, step length and stance time of the hemiparetic limb when using the DAFO, compared to walking with an AFO, or barefoot.

Mueller *et al.* (1991) tested a 55-year-old right side hemiplegic male wearing normal shoes or a DAFO, or walking barefoot. An AB-BA single-case design was used and foot-loading data were collected using a pressure-sensitive mat. The subject wore the orthosis for fourteen days between the tests. The results indicated that use of a DAFO gave greater foot stability during stance. Also total foot contact areas times were increased, which it was speculated, reflected better sensory input through the foot. Jain *et al.* (1995) evaluated the effects of a DAFO on the gait, trunk movement, and upper extremity function of an adult patient with dystonia. The data from gait analyses were assessed visually from video pictures and the subject's satisfaction monitored via interview. This study indicated that the orthosis decreased pain and also improved the

initial contact of the foot and decreased lateral trunk flexion. Improved left upper extremity function was also evidenced by the ability to carry an object in the left hand during gait.

Wolley *et al.* (1996) studied balance and gait in five subjects, with a mean age of 48 years, six to twelve months after a stroke or traumatic brain injury. In this study, subjects were randomly fitted with an AFO or DAFO that was worn for four months, after which they received the alternative orthosis for four months. The standing balance was tested using a force platform, and joint kinematics, kinetics and spatio-temporal data were recorded with two cameras in the frontal and sagittal planes. The left and right side of the subjects' gait were recorded separately. The authors reported no statistically significant differences in walking ability between barefoot, or when using the AFO or DAFO. However, it was suggested that DAFOs might have a greater impact with more severely disabled subjects, for whom it may be easier to identify improvement effects. More recently, Deli *et al.* (1997) followed three subjects in singe-case studies in which subjects used DAFOs or AFOs, or walked barefoot, in randomly assigned order. The gait stride characteristics were recorded using foot-switches and time-distance parameters were analysed. The results showed that gait velocity, stride length, cadence and single-limb support were increased using DAFOs compared to the other conditions. The authors concluded that the results indicated more symmetrical gait using DAFOs with these three stroke patients.

It is clear that from the information above that the role of DAFOs in the therapy of adult neurologically impaired patients is also only in the early stages of objective evaluation. Thus, whilst some studies have demonstrated positive application of DAFOs via single-case studies, their applicability, or otherwise, to stroke patient rehabilitation more generally has not been properly investigated. During recent years, DAFOs have been introduced in several European countries, but their use in stroke patient rehabilitation has been limited. This is probably because the decision to use orthoses is often made

without full knowledge of their benefits and limitations (Aisen, 1992), or because neurological rehabilitation is often based on therapy without supportive devices (Sackley and Lincoln, 1996; Lennon *et al.*, 2001). Given the debilitating effects of stroke on patients' mobility, further research in the field of orthotic intervention is needed urgently.

1.5 Rationale, hypotheses and aims of the study

1.5.1 Rationale

The introduction to this thesis described the impact of CVA on society and how mobility problems are a major influence on the quality of life following stroke. Although advances in drug treatments designed to minimize the clinical outcome of stroke are being made, at present there are no established pharmacological therapies. Effective neurological rehabilitation is therefore central to improving stroke patients' quality of life and functional independence. There is thus an urgent need for innovative approaches to the rehabilitation of stroke patients to meet the projected rise in the number of chronically disabled.

Whilst traditionally stroke rehabilitation, particularly in the UK, has focused on therapy without supportive devices, conventional AFOs are now sometimes used in an attempt to correct patients' mobility problems. These orthoses are presumed to limit ankle dorsiflexion, thereby supporting the ankle throughout the gait cycle. Recently, more sophisticated DAFOs, which exploit developments in fabrication techniques using more flexible materials, have also been introduced into some centres. There are preliminary indications that DAFOs might improve some spatio-temporal parameters of stroke patients' gait through their flexible and light construction. In addition, it has been suggested that the custom-moulded insole feature of DAFOs could provide beneficial proprioceptive feedback, as well as supportive control of the foot and ankle. However, most of the evidence for these ideas is circumstantial, being based upon limited single-case studies on less-severely disabled subjects with minimal gait deviation.

There have been no detailed clinical studies of how DAFOs influence lower limb movements during gait and standing. Thus, the efficacy and mode of action of these devices is poorly understood. Recent advances in knowledge of sensory/motor control support the theory that biomechanical and neurophysiological factors might be involved when using DAFOs to assist gait. As stroke is one of the most common and debilitating neurological conditions, which places a major burden on health resources world-wide, there is a great need to gain a better understanding of orthotic intervention involving DAFOs in stroke rehabilitation.

1.5.2 Working hypotheses

The points outlined above (section 1.5.1) can be formulated into three related hypotheses, the testing of which forms the basis for the original experimental studies described in this thesis.

1. *DAFOs improve motor behaviour after stroke involving the acquisition of standing balance compared with using shoes;*

2. *DAFOs also improve motor behaviour after stroke involving the acquisition of gait performance compared with using shoes;*

3. *The users' subjective opinions of DAFOs support the findings of DAFOs ability to modify human performance such that DAFOs are beneficial when used as a part of rehabilitation management for stroke patients.*

1.5.3 Aims of the research

The purpose of the research was to examine changes in the balance and gait of stroke patients associated with the use of this dynamic type of lower limb orthosis.

Specifically, the work aimed to:

1. Examine, over a three months testing period, whether the use of a DAFO changes standing balance (assessed via the centre of pressure position and horizontal force magnitude) after stroke compared to using casual shoes;

2. Investigate whether using a DAFO alters the spatio-temporal parameters (velocity, stride length, step length, cadence, stance phase, single stance phase) of gait compared to casual shoes;

3. Assess whether using a DAFO alters the kinematic parameters (linear/angular displacement of the ankle, knee and hip joints, and segmental angular displacement/velocities of the foot, shank, thigh and pelvis) of gait after stroke compared to casual shoes;

4. Determine whether stroke subjects' opinions of DAFO use via subjective questionaire assessment supports the notion of beneficial effects of the device.

2 METHODS

As DAFOs are a relatively new orthotic approach, there are no established procedures for studying their application to stroke patients. In addition, the biomechanical and neurophysiological relationships between motor performance and different rehabilitation methods are, at present, poorly understood. The original research undertaken here used experimental designs adapted from limited published studies using earlier types of orthotic intervention (section 1.7) and better documented methods for the general study of balance and gait parameters in stroke patients and healthy elderly adults (section 1.6). The work involved a randomised and controlled clinical trial designed to examine the effects of DAFOs on specific balance and gait characteristics of stroke subjects. In order to generate a comparative database, separate studies were made of healthy subjects' gait performance. The main methods used were biomechanical, and utilised a force platform and three-dimensional (3-D) movement analysis. In addition, stroke subjects' functional abilities during daily living were assessed via established clinical methods and by the subjects' own opinion of the DAFO using open-question interview.

The research was broadly separated into four phases, consisting of subject recruitment, pilot studies, method reliability assessments and the main testing trials. The subject recruitment phase utilised clinical information that enabled selection of appropriate stroke patients based on specific criteria in relation to disability levels. The pilot phase involved protocol and method testing with a limited number of stroke patients and healthy subjects. This work was done to allow development of the experimental methods and design, and to ensure that the subject selection and testing procedures were practical for clinical purposes. Thus, as most of the original research reported in this thesis involved studying severely disabled stroke subjects, at sub-acute stages of their rehabilitation, it was essential to firstly obtain a working knowledge of how such individuals could cope with potentially rigorous testing protocols in the gait laboratory. In addition to providing general information on research practicalities, it was predicted

that the pilot studies would 1) clarify the procedures and objectivity of the subject inclusion and exclusion criteria, 2) indicate the timescales required for fabrication of orthoses, 3) enable the author to develop proficiency in performing the experimental procedures, and 4) provide preliminary data on how DAFOs affect stroke patients' balance and gait. Consequently, these studies were undertaken during the early part of the subject recruitment phase. Assessments of method reliability were carried out on a regular basis throughout the duration of the research. The main phase consisted of balance, gait studies and subjective feedbakc on all of the recruited subjects, using methods that were appropriately modified from the findings of the pilot studies, and functional assessments.

It should be noted that whilst the pilot work did highlight aspects of the research design that required modification, overall, the protocols planned for the work were found to be entirely appropriate, requiring only minor changes. In some cases, changes were made simply because of the availability of newer and more modern instrumentation. For this reason, and for clarity, this chapter describes the definitive methods used for subject recruitment, and for the functional, balance and gait assessments; details of the pilot study, including methods, protocol changes implemented, and findings, are given in Appendix I.

All experimental procedures and measurements were conducted in a newly built gait laboratory facility within the School of Health Care Professions at the University of Salford. This laboratory is equipped with state-of-the-art instruments designed specifically for quantitative measurement of human motor performance. The overall design of the research is summarised in Figure 2.1.

2.1 Subject recruitment

Stroke patients admitted for rehabilitation to the Stroke Unit of the Salford Royal Hospitals NHS Trust (Ladywell and Hope Hospitals) were recruited for study. This

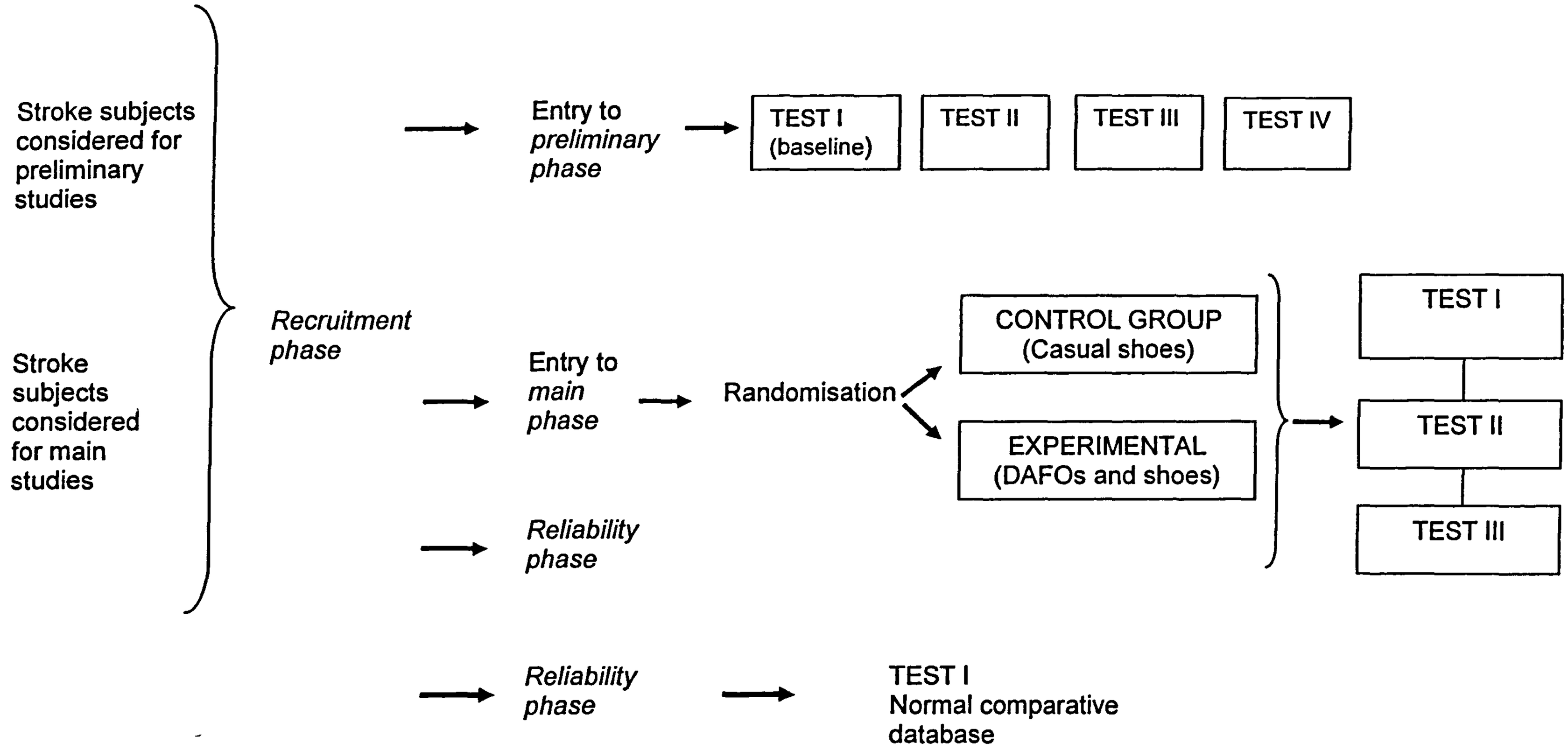


Figure 2.1 Summary of the research design. Details of the different testing procedures are provided later.

establishment is the main rehabilitation unit for acute CVA patients in the North-West of England. For this research, patients admitted over a two and a half year period were considered. Patient recruitment involved detailed clinical assessment and criteria evaluation before informed consent was sought from potential subjects.

2.1.1 Clinical assessment

In order to identify possible test subjects, the first stage of the recruitment process involved attending weekly ward rounds in the Stroke Unit, and consultation with senior medical staff. Multi-professional rehabilitation meetings specific for each newly admitted patient were also attended to obtain further information on potential subjects' medical conditions and mobility problems. The rehabilitation progress for each patient was then followed via weekly communication with the senior nurses and therapists in the Stroke Unit. After discharge from the Stroke Unit, arrangements were made for potential subjects to visit the Gait Laboratory for further assessment of their mobility and recovery. Where appropriate, a further meeting was arranged between the patients, their carers and the author, to determine willingness to be involved in the research.

The next stage of subject recruitment consisted of clinical assessment to provide a preliminary and standardized description of patients' mobility. The results were used to clarify inclusion criteria regarding the level of gait impairment and disability (described later) and to ensure that the patients were able to participate in testing trials that are physically demanding. Patients' gait impairment, including joint mobility and muscle strength, was assessed by the author at the hospital or, if the patients were already discharged from the hospital, in the Gait Laboratory at this University. Patients were asked to walk ten metres along a corridor, unassisted, or with their own walking aid. Gait difficulties were evaluated visually and the observations were recorded on a standardised form designed by the author. Standing and walking ability (e.g. dependence on walking aid, effort required, and safety) and passive joint motions of the lower limbs were assessed. After these initial assessments, muscle strength of the

patients' main muscle groups (ankle flexors/extensors, knee flexors/extensors, and hip flexors/extensors) were assessed manually according to the Medical Research Council Scale (Demeurisse *et al.*, 1980) with minor modifications (Appendix III). The values obtained from this test were used as an indication of muscle activity when prescribing the DAFO. In total, 195 stroke patients were evaluated.

2.1.2 Inclusion criteria

For any type of clinical trial, the criteria used for selection are important because their rigidity dictates the level of experimental interference by identified extraneous factors, and the applicability of the data to the general population (Wade, 1992; Motulski, 1995; Dirnagl *et al.*, 1999). Clearly, the recruitment and study of neurological patients involves some unique problems. For the present research, the design of subject selection procedures incorporated important physical, neurological, practical and safety considerations. The criteria adopted were that each subject:

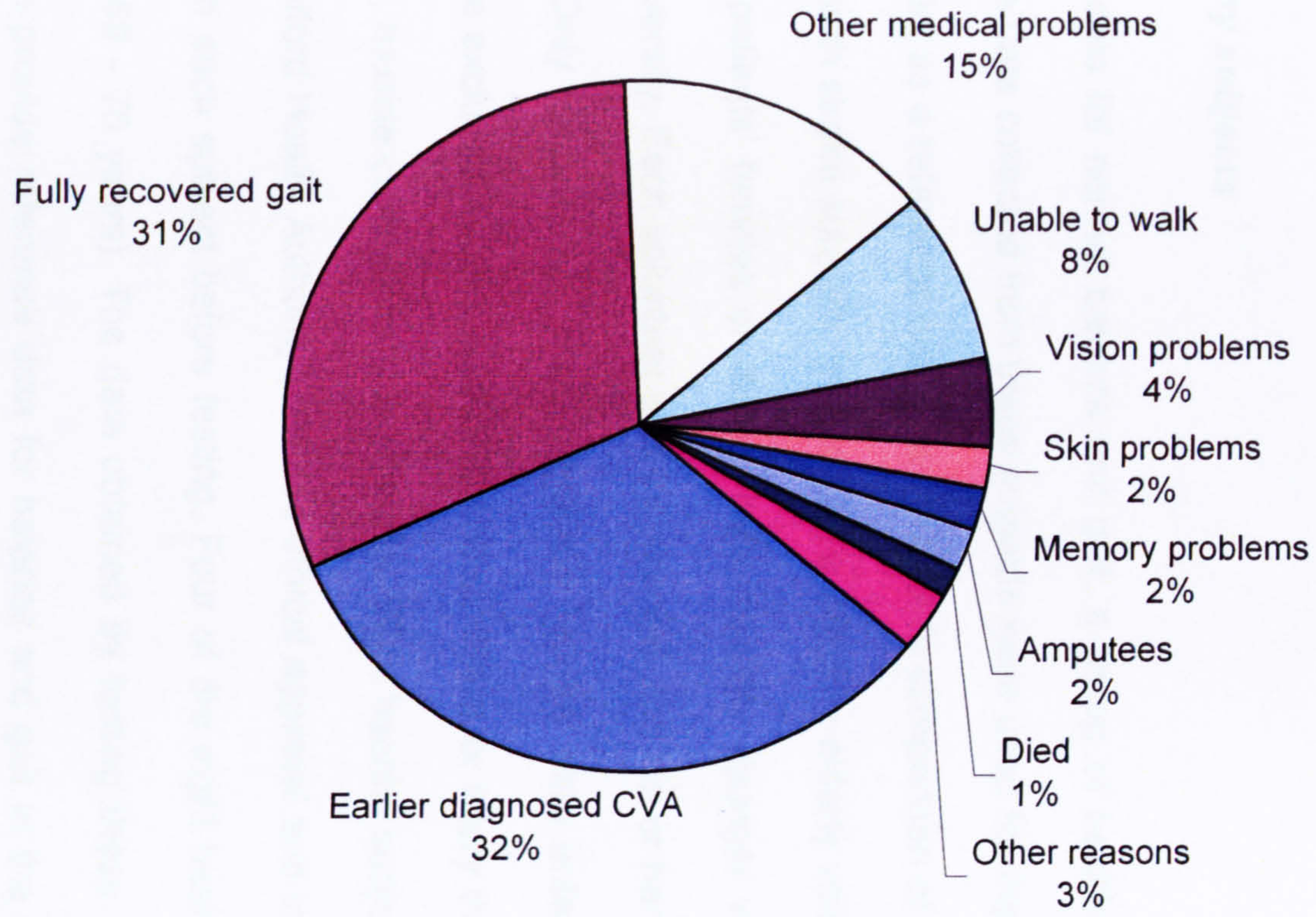
1) had no previous CVA;
2) was medically stable;
3) had no other medical problems after CVA that affected ambulation;
4) had no earlier diagnosed long-term mobility problems;
5) had no cognitive impairment such as memory loss, or difficulties in understanding normal speech;
6) could demonstrate at least ten-metre walking capacity without a break;
7) exhibited an assessable gait deviation that affected mobility and caused some disability.

A convention for studies of this type is that the experimental group is more uniform and measurements are more reliable if stroke subjects who have not suffered an earlier CVA are used. This is because subjects who have had an earlier stroke may have already learnt compensatory movement patterns, and shortening of soft tissues or joint

structures may have occurred, which could obfuscate data interpretation. It is well established that most 'natural recovery' following stroke occurs within three months of the initial insult (Smith *et al.*, 1985; Wade *et al.*, 1985; Kwakkel *et al.*, 1999) and consequently there is likely to be considerable variation in gait parameters at this time. It was therefore decided that the best strategy for testing the research hypotheses would involve testing a group of stroke patients with a similar type of gait impairment and after their initial recovery phase, when there are minimal changes due to compensatory learning of gait movements. It was clearly important to use subjects that were medically stable, and had no other ambulation or long-term mobility problems that could cause mechanical changes to joints or soft tissues and thus affect joint mobility (e.g. arthritis). The criterion for no cognitive impairment was applied for safety reasons and because the studies required that the subjects were able to understand written instructions and voice commands and be generally aware of the procedures. The criterion requiring patients to demonstrate at least ten-metre walking capacity without a break was adopted to ensure a minimal mobility level. Recognisable gait deviations included limited forefoot eversion, diminished ankle dorsiflexion or knee hyperextension, which are conditions that warrant the use of a splint.

It was predicted that on discharge from the Stoke Unit, around 80% of subjects would return to their own homes (Salford Royal Hospital NHS Trust, Executive Board Paper, 1995). Thus, the potential influence of DAFOs on balance and gait could be assessed after the devices had used by the subjects in their home environment and under familiar living circumstances. It was anticipated that a considerable number of subjects would have to be evaluated before a reasonable study group size was achieved, which meant that recruitment would be time-consuming. Thus, much of the time during the first twelve months of this four-year research project was devoted to subject recruitment. The outcome of excluding subjects on the basis of the criteria specified is shown in Figure 2.2. A register of admission was used to document the patients who met the

Figure 2.2 Analysis of reasons for exclusion of potential subjects from study.



Proportion of stroke patient who took part in the studies expressed as a percentage of the total number of subjects (165) considered. Inclusion was based on specific criteria, including neurological, physiological, practical and safety considerations (for details, see text). The other medical problems indicated were conditions that cause severe mobility problems such as swollen legs, arthritis, Parkinson's disease and cancer. Subjects that were unable to walk were generally wheelchair users.

criteria for inclusion. All subjects who met the criteria and were willing to participate in the studies were included. Of the 195 subjects considered, twenty-five passed the criteria and agreed to take part. All subjects were required to give written informed consent prior to participation in the studies. Ethical approval was obtained from the Salford Research Ethics Committee (code 95146) and all experiments were conducted in accordance with the provisions of the Declaration of Helsinki. Subjects' prescribed medical and rehabilitation care was continued during the experimental period.

2.1.3 Healthy subjects

To generate data for normal balance and gait, a group of healthy subjects was also recruited. The data collected from these subjects were used for the reliability tests, and in the main trial as a reference database, to enable comparison of normal balance and gait patterns with stroke subjects' performance. Healthy elderly volunteers were usually members of patients' families or their friends. Healthy younger volunteers were staff from this University. Each volunteer was interviewed and his or her medical history was determined. Only subjects who were physically healthy were entered into the studies. Subjects were excluded if there was evidence of illness or injury that could cause pain, joint stiffness, muscle contraction or weakness. Eight healthy subjects were admitted to the study. Salford Health Authority provided ethical approval and informed consent was obtained from each subject before testing. Four of the eight healthy subjects were of similar age (69 - 70 years). The data obtained by testing these able-bodies subjects were used to provide reference data for balance and gait in the main study involving stroke patients. The other four subjects were younger (23 - 38 years) and data obtained were used for reliability tests of balance and gait methods. Subject details are given in Table 2.1.

Table 2.1 Subject details (healthy)

Subject code	Age (years)	Gender (M/F)	Weight (kg)	Height (cm)
Older subjects				
C01	69	M	88.5	170
C02	69	M	73.5	175
C03	70	F	64.0	152
C04	69	F	67.0	158
Mean	*Range*	2 M, 2 F	*73.3*	*163.8*
69.3	*69-70*		*64.0-88.5*	*152-175*
Younger subjects				
C05	23	M	66.5	173
C06	38	F	66.5	176
C07	26	F	60.0	168
C08	34	M	90.5	189
Mean	*30.3*	2 M, 2 F	*70.9*	*176.5*
Range	*23-38*		*66.5-905*	*168-189*

2.2 Experimental design and testing procedures

2.2.1 Experimental design

A randomised experimental design was used to assess the effects of DAFOs on each of the balance and gait characteristics. Stroke subjects (n = 22) were randomly allocated to one of two groups, consisting of a control group (Table 2.2) in which the subjects wore their own casual shoes without a splint, and an experimental group (Table 2.3) in which the subjects wore DAFOs on the side affected by the stroke. A randomised design was used in order to keep the experimental and control group characteristics (described below) as equal as possible. This was achieved using the appropriate algorithm procedures within StatMate™ (GraphPad Software Inc.), assigning 11 subjects to each group. Using this method, the control group comprised five female and six male subjects with a mean age of 67 years; three had right side and seven left side hemiparesis. The time since diagnosis of stroke was 4-15 months prior to recruitment. The experimental group comprised four female and seven male stroke subjects who also had a mean age of 67 years; six had right side hemiparesis and five left side hemiparesis. The time since stroke was diagnosed was 4-18 months. The demographic characteristics for both groups are summarised in Table 2.4.

The subjects in both groups were tested on three occasions (three separate testing sessions) over a twelve-week period. The first tests were carried out four to six weeks after achievement of the inclusion criteria, when the experimental group had become familiarised with their DAFOs. The second tests were conducted four weeks later and the final tests after a further eight weeks. For the remainder of this thesis these tests are referred to as week 1 (test I), week 4 (test II) and week 12 (test III). During each testing session, control subjects were tested twice with shoes alone; experimental subjects were tested with and without their splint (in randomised order). The testing

Table 2.2 Subject details (control group)

Code	Age	Gender	Diagnosis/TS (months)	Side of paresis	Walking aid inside/ outside
C01	76	M	Infarct/ 4	Left	No / WCH
C02	74	F	Infarct/ 8	Left	No / WCH
C03	54	M	Infarct/ 6	Right	No / WCH
C04	68	M	Infarct/ 15	Left	No / stick
C05	75	F	Infarct/ 4	Left	Stick / WCH
C06	66	F	Infarct/ 5	Left	Stick / WCH
C07	52	M	Infarct/ 7	Left	No / no
C08	65	F	Infarct/ 11	Left	No / stick
CO9	67	M	Infarct/ 12	Left	No / no
CO10	64	M	Infarct/ 7	Left	Stick / stick
CO11	76	F	Infarct/ 3	Left	WFM / WFM

Table 2.3 Subject details (experimental group)

D01	64	M	Infarct/ 4	Left	Stick / WCH
D02	69	M	Infarct/ 5	Left	Stick / WCH
D03	75	M	Infarct/ 5	Left	Stick / WCH
D04	87	F	Infarct/ 4	Left	WFM / same
D05	65	M	Infarct/ 18	Left	No / stick
D06	54	M	Infarct/ 14	Right	No / no
D07	70	M	Infarct/ 4	Right	Stick / WCH
D08	67	F	Infarct/ 10	Right	Stick / WCH
D09	66	F	Infarct/ 7	Right	Stick / WCH
D10	72	M	Hae/ 11	Right	Stick / WCH
D11	49	F	Infarct/ 6	Right	WFM / Scooter

TS = Time since stroke; Hae = Haemorrhage; WCH = wheelchair; WFM = walking frame

regimes are shown schematically in Figure 2.3. Separate recordings of healthy age-matched subjects were interspersed with these measurements.

Table 2.4 Comparison of demographic details of the two stroke subject groups

Demographic characteristics of subjects				
Group	*Sex*	*Mean age in years and (Range)*	*Side of paresis*	*Time since stroke Mean and range*
Experimental *n* = 11	4 females 7 males	67.1 (49-87)	5 left 6 right	8 months 4-18 months
Control *n* = 11	5 females 6 males	67.0 (52-76)	10 left 1 right	7.5 months 4-15 months

2.2.2 Provision of orthoses

Each subject in the experimental group used a DAFO that was custom-designed and fitted for their particular needs. Fabrication was carried out three to five weeks after the subject satisfied the study entry criteria. For each subject, an appointment was arranged with an experienced orthotist and, following instructions by the author about patients' mobility problems (from the clinical assessments), a DAFO was constructed to suit the specific gait deficit. To enable appropriate casting, the subject's gait was evaluated subjectively at the hospital or in the subject's home. The orthotist manually appraised each subject's foot contour (bone shape, muscles and tendons) for building a casting model of the insole. The orthotist then constructed a plaster model of the subject's foot and ankle, which was sent to a commercial orthotic laboratory (Bullens Ltd., U.K) for fabrication of the orthosis. Details of the fabrication procedures used are given in Appendix II.

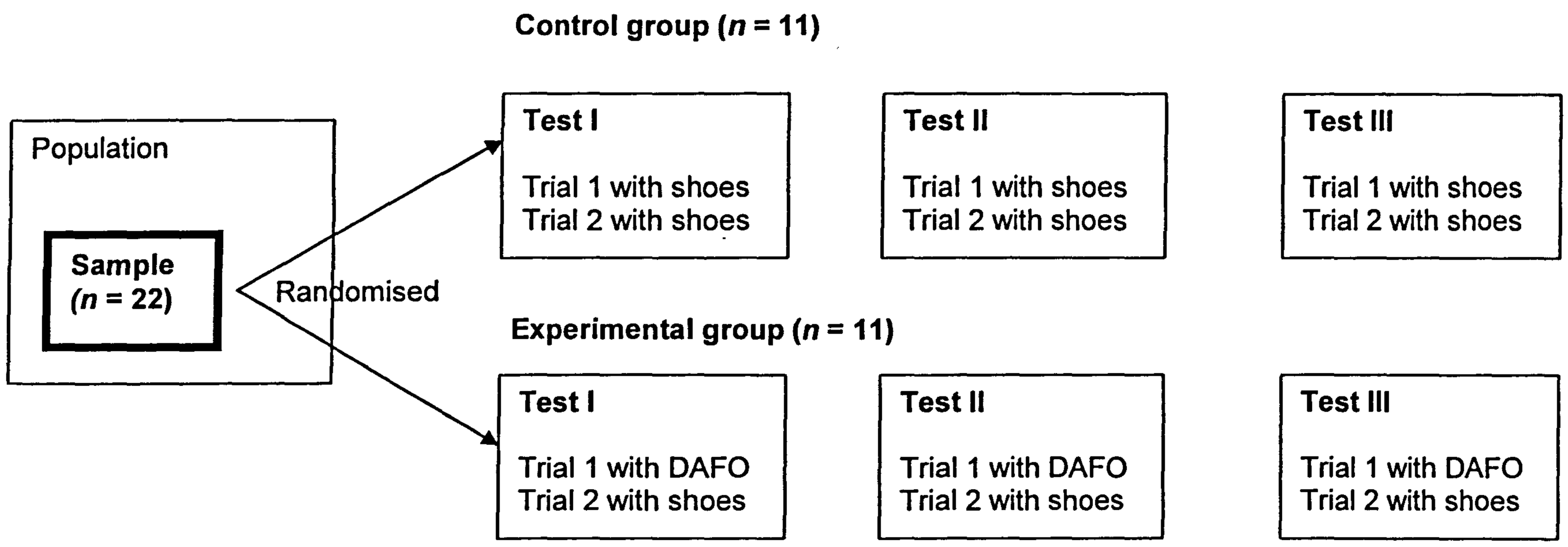


Figure 2.3 Schematic representation of testing procedures from the time of recruitment to the final test. The timing between randomisation and the first test took from four to six weeks. The follow-up period from the first test to the second test was four weeks; the final test was carried out eight weeks later.

2.2.3 Testing procedures

Arrangements were made to transport subjects from their home to the Gait Laboratory via private-hire taxi. Each testing session consisted of three separate parts: balance testing, gait analysis tests and functional assessments. For the balance and gait measurements, the experimental group was tested with and without their DAFO during each test; the order of testing was randomised to minimise the potential for interference of fatigue and repeated task learning on subjects' performance. The control group followed the same procedure wearing shoes. The testing procedures that were undertaken are summarised in Table 2.5.

Balance tests were performed a total of eight times (four times with DAFOs and four times with shoes) providing that the patient did not become fatigued, giving a total of (twenty-four separate measurements over the three testing sessions). During each test, subjects were tested twice with their eyes-open and twice with eyes-closed using the DAFO. This procedure was then repeated with shoes alone. During the eyes-open tests, subjects were encouraged to keep their gaze forward, on a target placed at eye level on a wall three metres in front of the platform. For the eyes-closed tests, subjects were asked to look at the same target before firmly closing their eyes. Control subjects followed the same procedures. The healthy subject (using shoes) tests were identical except that all tests were conducted sequentially during one session.

Before the gait test commenced, the subject was instructed to walk at their most comfortable speed and to keep the walkway guide to their right side. The subject was asked to walk with their head up, looking forwards and as naturally as possible. The first trial was used as a 'practice', to familiarise subjects with the procedure, and was not included in the data analyses. Subjects then completed a minimum of four and a maximum of six repeated gait tests, depending on their physical condition. It was endeavoured to record two or three separate tests with and without the DAFO. Between each test, the patient sat down for a ten to fifteen minute break. A nurse was present to

deal with any emergencies and to assist the subject if necessary. All gait data from foot-pressure sensors and camcorders were recorded simultaneously (described later).

Table 2.5 Testing procedures: the first test represented the stating point, which was followed by two further tests over twelve weeks. Each testing session consisted of balance, gait and functional assessment tests. For details, see text.

	TEST I	**TEST II**	**TEST III**
	week 1	**week 4**	**week 12**
Control group - tested twice with shoes alone	1) Balance tests 2) Gait tests 3) Functional tests	Measurements repeated	Measurements repeated
Experimental group - tested once with DAFOs and once with shoes alone	1) Balance tests 2) Gait tests 3) Functional tests	Measurements repeated	Measurements repeated

2.3 Functional assessments and subjective feedback

Subjects' gait impairment, disability and functional ability during every day life were evaluated using functional assessment scales suitable for stroke patients. These assessments were undertaken because of difficulties in interpreting clinical notes due to ambiguities arising from contributions from different therapists and clinics. The first scale employed was the Rivermead Motor Assessment (RMA) scale (Appendix III). This is a routine questionnaire (by interview) system used to evaluate changes in patients' impairment and disability using scorable measurements of motor function (Lincoln and Leadbitter, 1979). It is based on the assumption that stroke patients follow a consistent pattern of recovery (Adams, 1995). The scale consists of two parts: a Gross Functional assessment and a Leg and Trunk assessment. Items in each assessment are chosen to

reflect the abilities of stroke patients at all stages of recovery. The scoring system (1 or 0) is dichotomous, so that a patient passes or fails each item of each section. The summed total of items passed in each section is recorded and an increase in the score of the RMA is indicative of motor recovery.

The second functional assessment used was the Nottingham Extended Activities of daily Living (ADL) index (Appendix III). This questionnaire (by interview) system focuses on the ability to carry out more difficult functional tasks, such as using public transport, housework, social life and hobbies (Nouri and Lincoln, 1987). Scoring (0-63) occurs in four areas: mobility, kitchen tasks, domestic tasks, and leisure activities. The scale is hierarchical, with higher values indicating better functional abilities. Assessment using the Nottingham ADL scale have shown a generally high test and re-test reliability (Lamontagne *et al.*, 2001).

Both the Rivermead Motor Assessment and Nottingham ADL scales are designed for use in both clinical and research settings and are deemed valid for such applications. The Nottingham ADL scale in particular is well established as being valid for determining whether any changes seen in disability and impairment translate into changes at the level of handicap and quality of life (Nouri and Lincoln, 1987). Both systems have been shown to have acceptable validity and good reliability when used clinically with stroke patients (Lincoln and Leadbitter, 1979; Collen *et al.*, 1990; Adams, 1995; Lamontagne *et al.*, 2001).

Functional assessments were carried out in the laboratory after the experimental trials. In each case, the author interviewed the subject and documented their responses to the items of the scale. After completion of the assessments, experimental subjects were asked for their opinions regarding the use of DAFOs via an open questionnaire (Appendix III). Subjects' opinions were scored on a non-specific rating scale from overall comfort or difficulty when using the orthosis. In this system, a response of 4 = no problems, comfortable, 3 = mostly comfortable, 2 = sometimes difficult, 1 = always

difficult, 0 = always very difficult, uncomfortable. This subjective feedback was also used by the orthotist when determining whether any modifications of an orthosis were required.

2.4 Balance measurements

The measurement of standing balance was carried out first at every testing session. On arrival at the gait laboratory, the experimental procedures were described to the subject, who was then offered a short rest (up to 15 minutes) before testing commenced. The subject changed into a light shirt and shorts. Subjects' static standing position was recorded using a piezoelectric-based force platform (Kistler Instruments Ltd.) connected to a PC running BIOWARE™ software. The force platform is a six-component load transducer capable of measuring the three-force and three-moment components required to completely describe the loading characteristics of a body in contact with a surface. The platform is a rectangular aluminium plate (40 x 60 cm) supported at each corner by a stack of three piezoelectric crystals arranged with their axes mutually orthogonal to give the three components of force at each corner, Fx, Fy, and Fz (Figure 2.4). These twelve channels from the four three-component force transducers are connected such that a total of eight outputs are given (described below).

The subject was instructed to step on to the force platform and to remain stationary looking forward with their head upright, eyes-open, and with their arms at their sides. The subject's feet were placed parallel and approximately 8 cm apart. This posture represents a natural standing position and keeps the feet inside the force platform perimeter (Figure 2.5 a). The position of the shoes was outlined with a marker pen so that the placement of the feet could be replicated for each trial. The subject was then asked to maintain this position without hand support for 30 seconds, with their eyes-open, during which time the forceplate output were recorded. After data collection, the subject was instructed to step off the force platform and asked to sit down to rest if

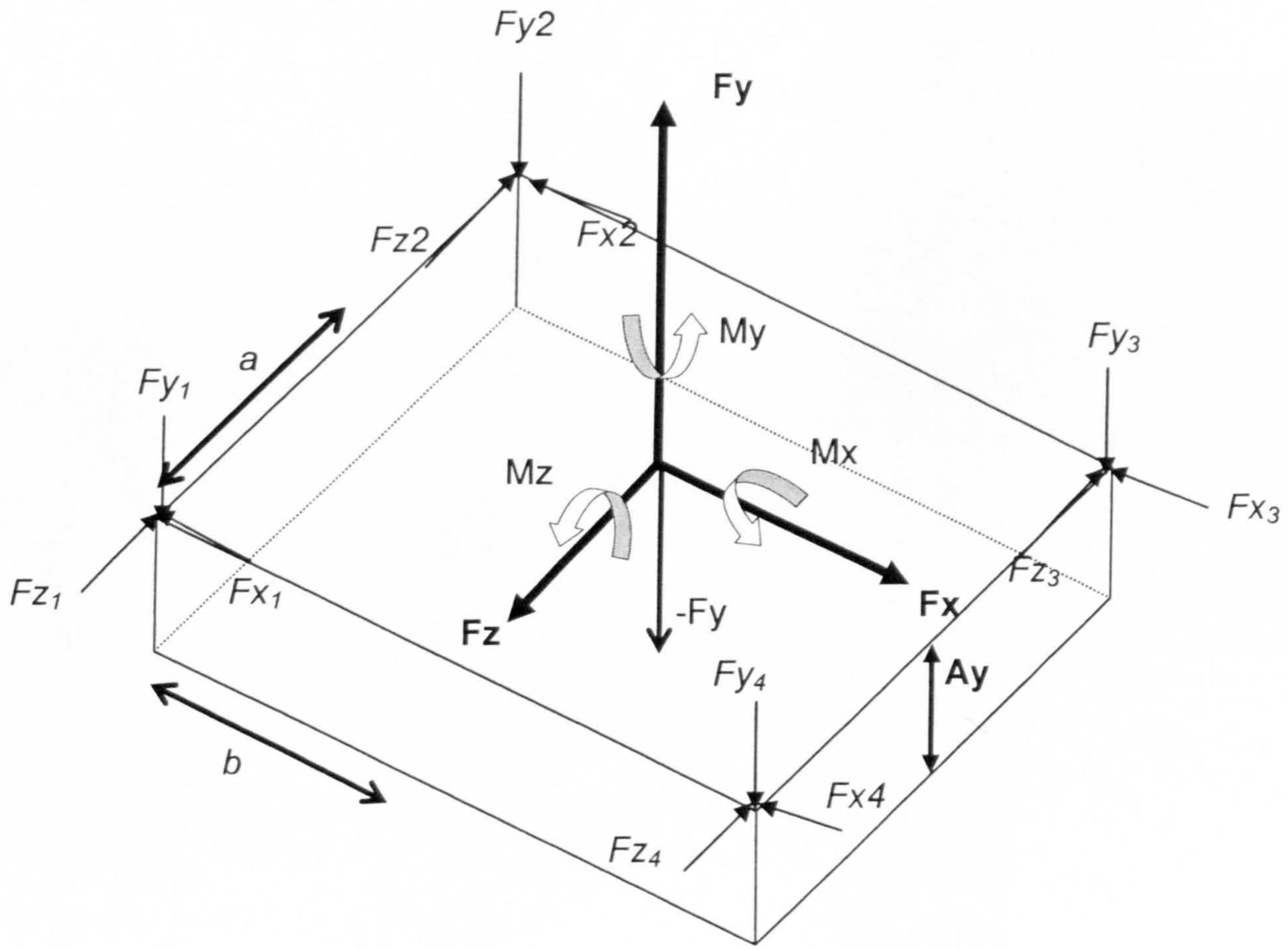


Figure 2.4 Schematic representation of the twelve individual force components measured by a piezoelectric force plate. The eight outputs from the force plate are (Fx1 + Fx4), (Fx2 + Fx3), (Fz1 + Fz2), (Fz3 + Fz4), Fy1, Fy2, Fy3, and Fy4. Subjects stood on the force platform facing towards the Fz direction (for details, see text).

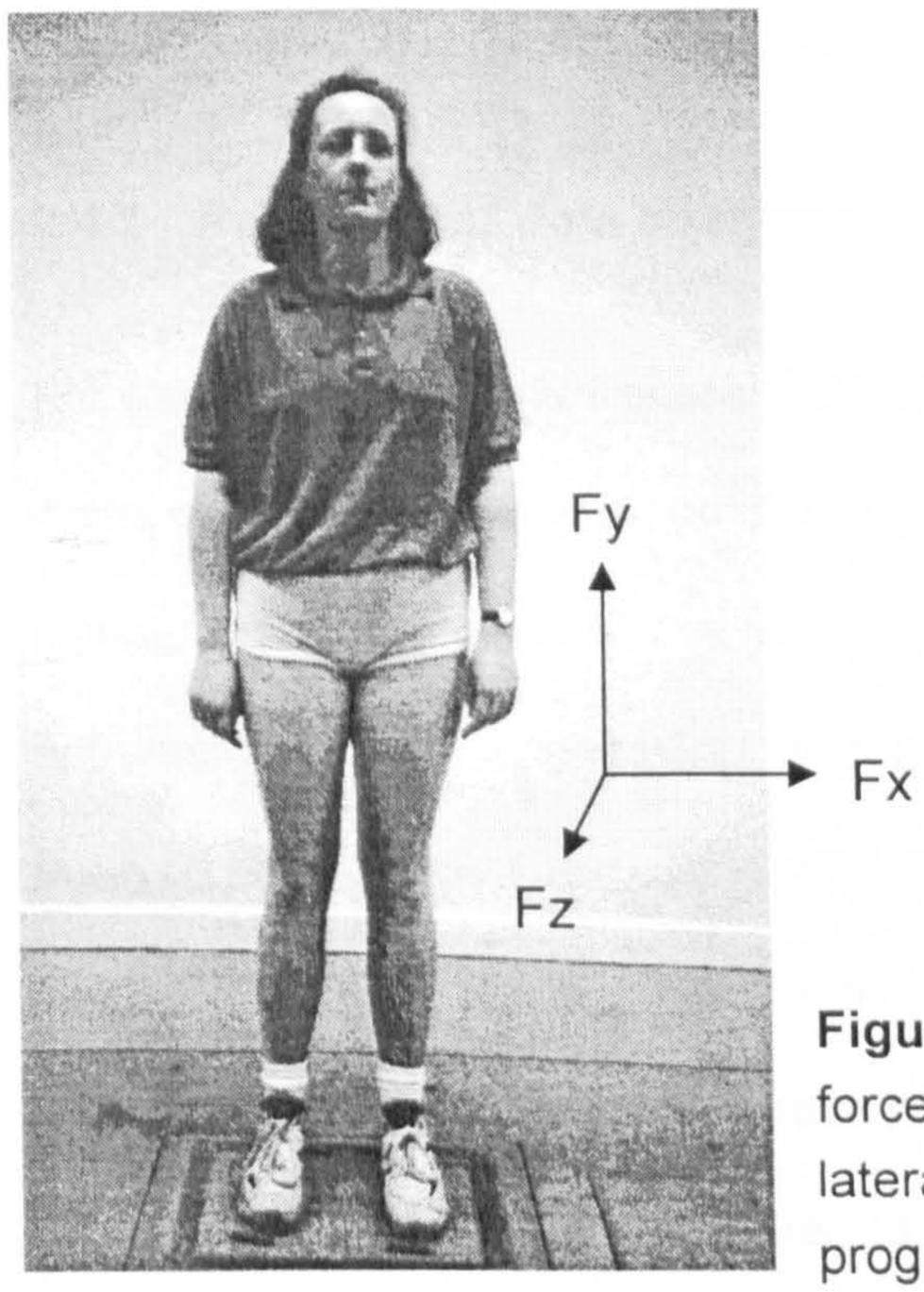
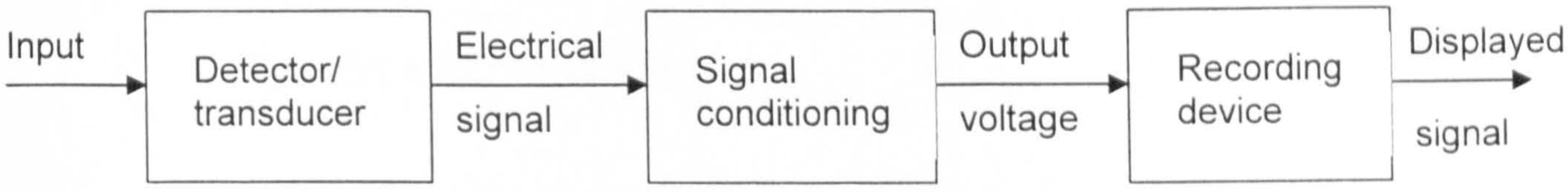


Figure 2.5 a) Balance measurement using the force platform. The vertical direction is Fy, the lateral direction is Fx and the direction of progression is Fz (for details, see text).

b)



c)

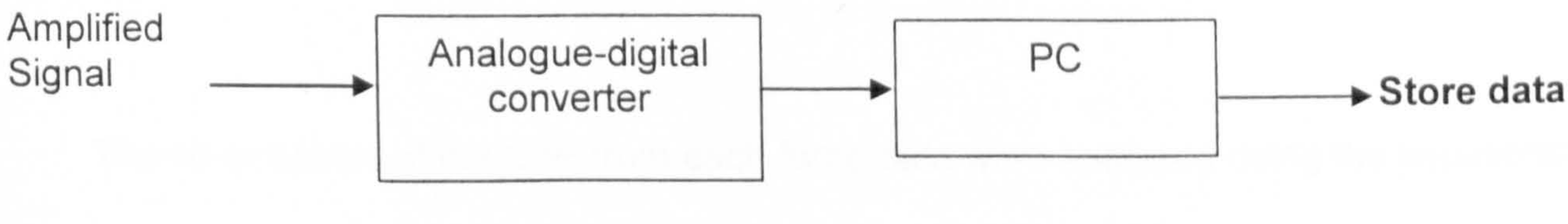


Figure 2.5 b) Schematic representation of the force platform system and **c)** set-up used to produce a signal in a form appropriate for digital computer processing via an analog-to-digital converter.

required. These tests were performed 8 times in total: 2 times with eyes-open and eyes-closed wearing the DAFO and with shoes only.

2.4.1 Balance test data analyses

For each test, the loads transferred between the force plate and the body in contact with it are expressed by a resultant force and a resultant moment, which were recorded. All signals from the transducers were amplified and acquired using analogue-to-digital conversion at 50 Hz sampling frequency, and stored (Figure 2.5 b and 2.5 c). Data analysis was carried out using dedicated software (Biomechanics Software Analysis System™, Version 2.0, Kistler Instruments). The eight channels represent the four individual vertical forces measured, two shear forces in the x-direction, and two shear forces in the y-direction. In order to determine the six ground reactions forces and moments, the data were further reduced as follows:

$$Fx = Fx1 + Fx2 + Fx3 + Fx4$$

$$Fz = Fz1 + Fz2 + Fz3 + Fz4$$

$$Fy = Fy1 + Fy2 + Fy3 + Fy4$$

$$Mx = (Fy1 + Fy4 - Fy2 - Fy3)a$$

$$Mz = (Fy1 + Fy2 - Fy3 - Fy4)b$$

$$My = b(Fz4 + Fz3 - Fz1 - Fz2) + a(Fx2 + Fx3 - Fx1 - Fx4)$$

The co-ordinates of the CoP from each force data were analysed using the equations:

$$Az = (- Mx+Ay*Fz) / Fy$$

and

$$Ax = (Mz+Ay*Fx) / Fy$$

where Ay is the distance from the force plate origin to the top surface (floor covering) and Az and Ax are the Z - and X -coordinates of the CoP measured from the centre of the force plate. The displacement of the CoP in the a-p and lateral directions was positive if the subject swayed in the anterior direction and to the left.

The total distance that the origin of the ground reaction force vector travelled during the recording period (30 s) was used to calculate the velocity of sway, which is defined as a control for static standing (Era *et al.*, 1996; Nougier *et al.*, 1997; Pushpangadan *et al.*, 1999).

In addition, body sway (sway index) was quantified by calculating the SD of the CoP displacement as a function of time (Era *et al.*, 1996), which indicates the range of motion of the point of application of the ground reaction force, and is typically used as a measure of stability of a subject standing on a force plate (Winter, 1991b; Saunders *et al.*, 2002).

Monitoring of these CoP variables has been advocated as the most practical static standing balance techniques for assessment of balance using a force plate with healthy and neurologically disabled subjects (Browne and O'Hare, 2001). The literature contains accounts of studies in which these variables have been used to correlate human balance, gait and muscle strength (Ringsberg *et al.*, 1999). Here, additional measurements made in the eyes-closed condition were included to provide further information on possible sensory effects of balance control (Lee and Lishman, 1976; Woollacott, 1993; Nougier *et al.*, 1997). CoP variables for antero-posterior and lateral sway were calculated separately, because they are due to different control mechanisms (Manchester *et al.*, 1989). The a-p component of CoP displacement in static standing is controlled by ankle plantarflexions and dorsiflexors, and the lateral component is controlled predominantly by the hip abductors and, to a lesser extent, by the ankle invertors and evertors (Winter, 1995).

The measured horizontal forces, Fx and Fz, applied to the surface of the force platform (Figure 2.4) were calculated. These horizontal (shear) forces were used because they describe the accelerations of the centre of mass. These accelerations represent the vibrations of the centre of the body or the spectral characteristic of the postural control (McClenaghan *et al.*, 1995). It has been suggested that this property provides a more sensitive means of identifying impaired balance in complex neurophysiological systems compared to the measurement of the resultant ground reaction forces under both feet (McClenaghan *et al.*, 1995; Nadeau *et al.*, 1999b; Kejonen and Kauranen, 2002). Fast Fourier Transformation was used to estimate the frequency composition of the forces (F) and to calculate the power spectra (resolution 50 Hz, bandwidth 0.05 - 10), and was used as each subject's spectral signature. This was done to characterise the postural control of each subject. F(mean) of the frequency analysis were designated as a central tendency. F(sd) is a distribution of spectral energy around F(mean), and F(slope) represents the slope of a regression line calculated on a double log axis plot of the power spectrum. The formulae used to extract dependent measures are published elsewhere (McClenaghan *et al.*, 1995) and included in Appendix IV. In the present studies, the F(mean), F(sd) and F(slope) are reported, because each may provide different sensitivities when describing difficulties in balance control (McClenaghan *et al.*, 1995; Williams *et al.*, 1997).

2.4.2 Validity and reliability of the force platform

Force platform apparatus is generally straightforward to use, providing that it has been correctly installed, and connected to appropriate auxiliary equipment (Bartlett, 1997b). However, as with all instruments used for gait analysis, it is essential to monitor for proper operation. Furthermore, valid and reliable force platform measurements depend on adequate system sensitivity, low threshold of force detection, high linearity, low hysteresis, low cross talk and the elimination of cable interference, electrical inductance and temperature and humidity variations. For a detailed description of factors that

influence force plate reliability and validity see Bartlett (1997a). For the present investigations, extensive preliminary studies were carried out using healthy subjects, to ensure that data compatible with earlier published reports could be obtained. This was essential in order to be fully confident that the testing protocol was reliable for clinical purposes. Calibrations were carried out on a regular basis during the course of the research. For example, calibration of the amplifier output as a function of force input was carried out according to the manufacturer's specifications.

The reliability measurements of standing balance followed similar testing protocols and data processing methods to those described earlier for the main balance tests. Thus, reliability was analysed within- and between-sessions. Here, practical difficulties were encountered when arranging for the elderly subjects to attend the gait laboratory. For this reason, the reliability work also included measurements of younger healthy subjects. The logistics for these procedures meant that healthy elderly subjects were used for within-session testing, whereas younger healthy subjects were involved with the between-session measurements. This arrangement was unavoidable. However, despite the less-than-ideal testing design, it was predicted that adequate information on reliability assessments for standing balance would be gained, which could then be compared with earlier published data.

Eight separate trials were performed for the testing of within-session reliability. Data for individual balance characteristics were firstly recorded from 4 repeated trials. After the subjects rested briefly, the measurements were repeated 4 further times. For the between-session reliability tests, the balance measurements were repeated at two-weekly intervals during the first 6 weeks and then at weeks 12 and 14. Data manipulation and parameter calculations were done as described earlier (section 2.4.1); the coefficient of variation (C.V. = SD/mean*100) of the repeated measurements was used to define reliability (Hicks, 1995).

2.5 Gait measurements

For every testing session, gait measurement assessments were carried out after the balance tests. Gait tests consisted of simultaneous recordings of subjects' gait characteristics and lower limb joint motions on a 10 m walkway using two different techniques: step-analyser and video-based movement analyser systems.

2.5.1 Step-analyser

The step-analyser system involves a foot-switch system, which monitors pressure data from four plantar locations, and provides details of the foot-fall parameters of the subject's foot during walking. The step-analyser (Figure 2.6) consists of four main components: a force sensitive resistor assembly (FSR), a data-logger, a receiver box with a small remote signal sensor, and two infrared beam transmitters. The FSRs used were flat plastic disks (2.5 cm × 0.4 mm), which contain pressure sensitive switches. These sensors have the advantages of being flexible and durable, with high overload tolerance and are of simple electronic construction (Bartlett, 1997b). A 440 N compression load cell and preamplifier were used for dynamic calibration of the FSRs. This calibration regime provides time-varying loads with durations modelling those of stance phase foot contact (Walsh, 1995). Acceptable validity and reliability levels for the step analyser used for the present work has been established with normal and neurological impaired subjects in earlier studies, and shown to be suitable for clinical gait assessment (Dr. T. Howe, personal communication).

One FSR was taped under the subject's heel and one under the third metatarsal at the interface between the foot and the shoe for control subjects, and between the shoe and DAFO for experimental subjects. Data from both feet were measured simultaneously. The four FSRs were connected via thin cables to the data-logger, which collected the output from the sensors at a rate of 200-500 samples per second, for a maximum of 32 seconds. The data-logger was attached to the receiver box, which stored the data

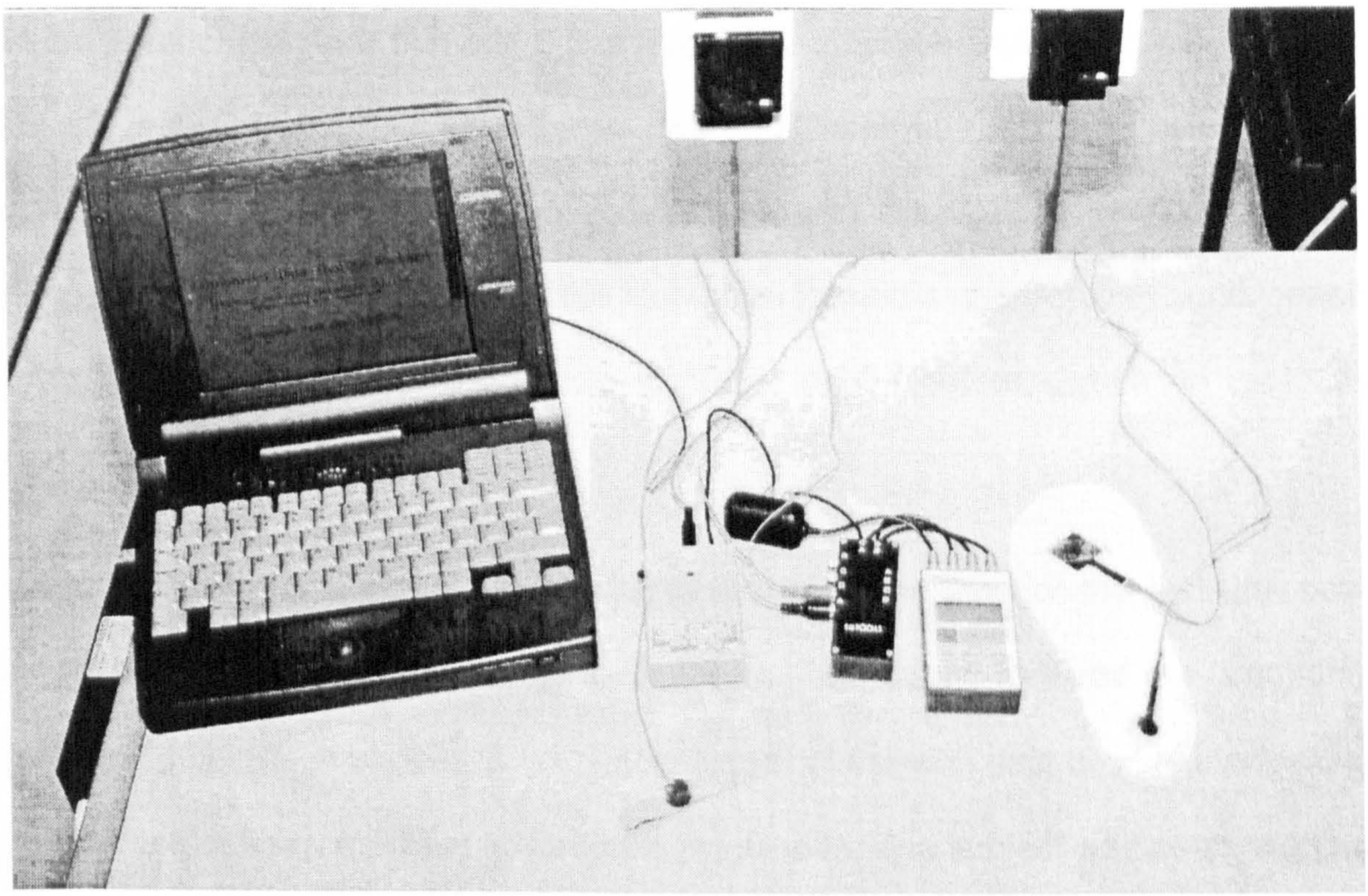


Figure 2.6 The step analyser consists of four main components: a force sensitive resistor assembly (FSR), a data-logger, a receiver box with a small remote signal sensor, and two infrared beam transmitters. The data were transferred to the PC for further analysis.

during the gait test. The step-analyser module was then located inside a small belt-pocket, which was attached around the subject's waist. The receiver box was connected to a small (1 cm diameter) remote signal sensor that is sensitive to infrared light (Figure 2.7). The remote signal sensor of the receiver was taped firmly to the front of the subject's right ear.

A 10 m walkway was demarcated on the gait laboratory floor. A black strip of thin plastic material was taped near to the right side of the walkway to act as a guide. Further guides were located at 2.5 m and 7.5 m intervals across the walkway to define a central 5 m active region where gait measurements were recorded (described below). The 2.5 m section at the start provided an acceleration area allowing the subject to attain a steady gait speed and rhythm, and the last 2.5 m formed a decelleration zone, enabling continuous walking to the end of the recording region before slowing to a standstill (Figure 2.7).

A chair was placed at each end of the walkway. At the start of the test, the seated subject was instructed to 'stand up' and, after a short delay, received the command to 'go'. The subject then walked the complete length of the walkway, at self-selected pace, whist aiming to keep the floor-guide to their right side. The subject was permitted to use their usual walking aid. The on/off controls for the data collection switch were operated manually. Infrared transmitter boxes were placed parallel to the acceleration- and decelleration-zone guides. When the subject walked past the infrared beam, the receiver box was activated by the remote signal sensor, and superimposed a marker spike on the foot pressure data. Walking past the second transmitter caused another spike. These data spikes enabled the data collected within the 10 m active region of the walkway to be identified easily and specified accurately. Subjects completed 4 - 6 trials, depending on the number of successful recordings and/or the subject's physical condition.

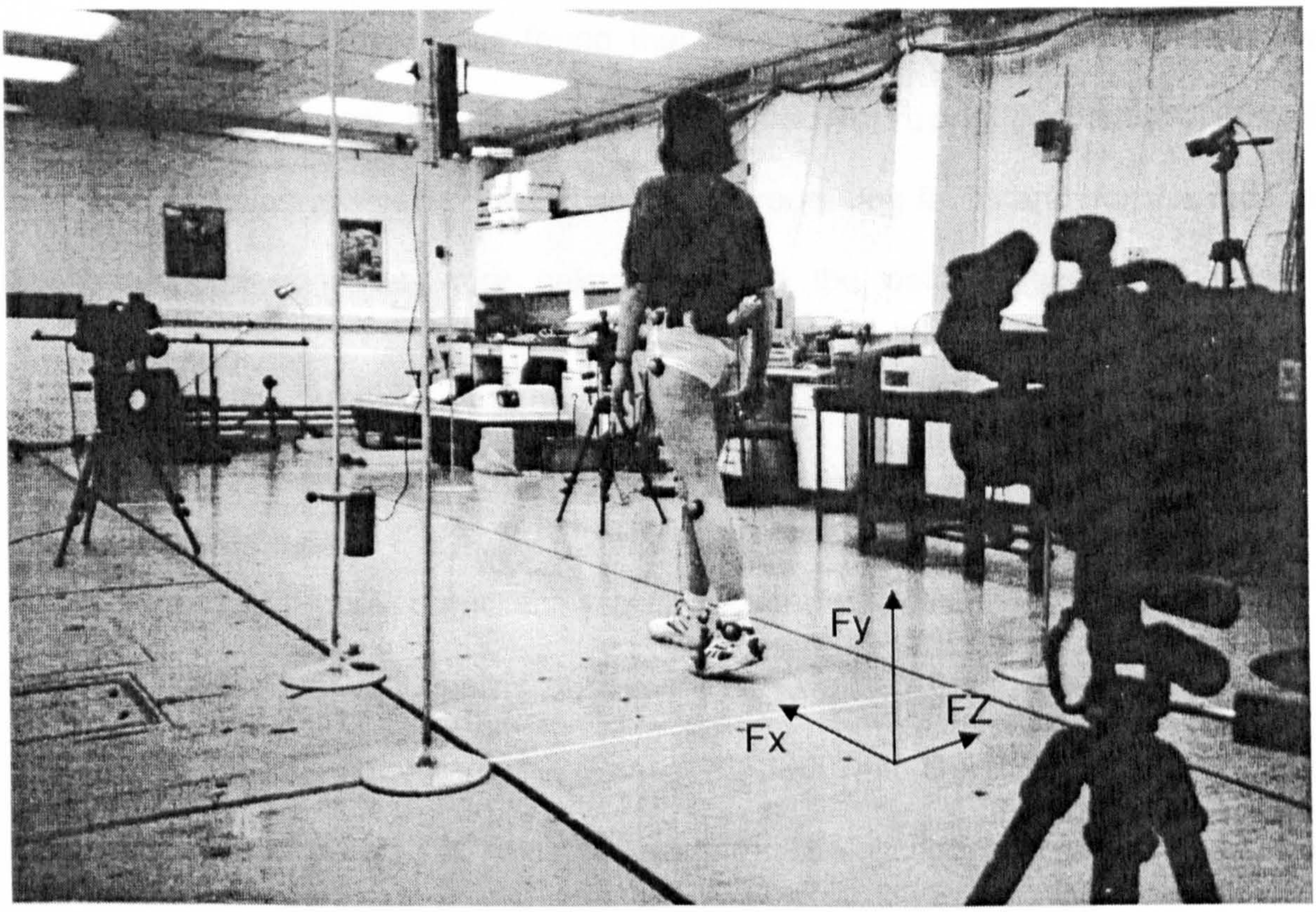


Figure 2.7 Subject's gait test in the gait laboratory. Twelve skin markers were attached with double-sided tape to the subject. The Step-Analyser module was then located inside a small belt-pocket around subject's waist. The subject was instructed to walk at their most comfortable speed and to keep the walkway guide to their right side (for details, see text).

2.5.1.1 Data analysis

The step-analyser recorded the timings of the point of contact during the stance phase and at the point of loss of contact during the swing phase. The data output from the receiver box was downloaded as ASCII files to a computer. The stored data generated from each sensor was analysed using MOTAN™ software (Dr. G. Barton, personal communication).

During data processing, it was found that data collected by the step-analyser were variable and could not be adequately accounted for using conventional analytical methods. Systems analysis revealed software-processing faults and, for this reason, all spatio-temporal variables were calculated from the data collected using the 3-D movement analysis.

2.5.2 Three-dimensional movement analysis system

Three-dimensional movement analysis was used to evaluate the motions of the subjects' lower limbs and pelvis during a 10 m walking test. The subjects' gait was recorded using four video cameras (Panasonic 3000 with S-VHS videotapes) operating at a frame rate of 50 Hz (50 fields per second). The recording area was limited to the central region of the 10 m walkway. Two cameras were situated at the front of the walkway angled at 80-degrees to each other; the other two cameras were positioned similarly at the rear of the recording area, approximately 5 m from the mid-point of the recorded view (Figure 2.8). This camera arrangement has three benefits: firstly, it helps to minimise problems due to the 'hidden body part' phenomena where, for example, an arm hides a hip marker from camcorder 1, although camcorders 2 and 4 can still follow the marker; secondly, it permits simultaneous recording of the left and right legs during each gait test, which facilitates more accurate and comparative data interpretation; and thirdly, it reduces the number of tests required and is therefore physically less demanding for elderly, disabled subjects. The position and number of the cameras

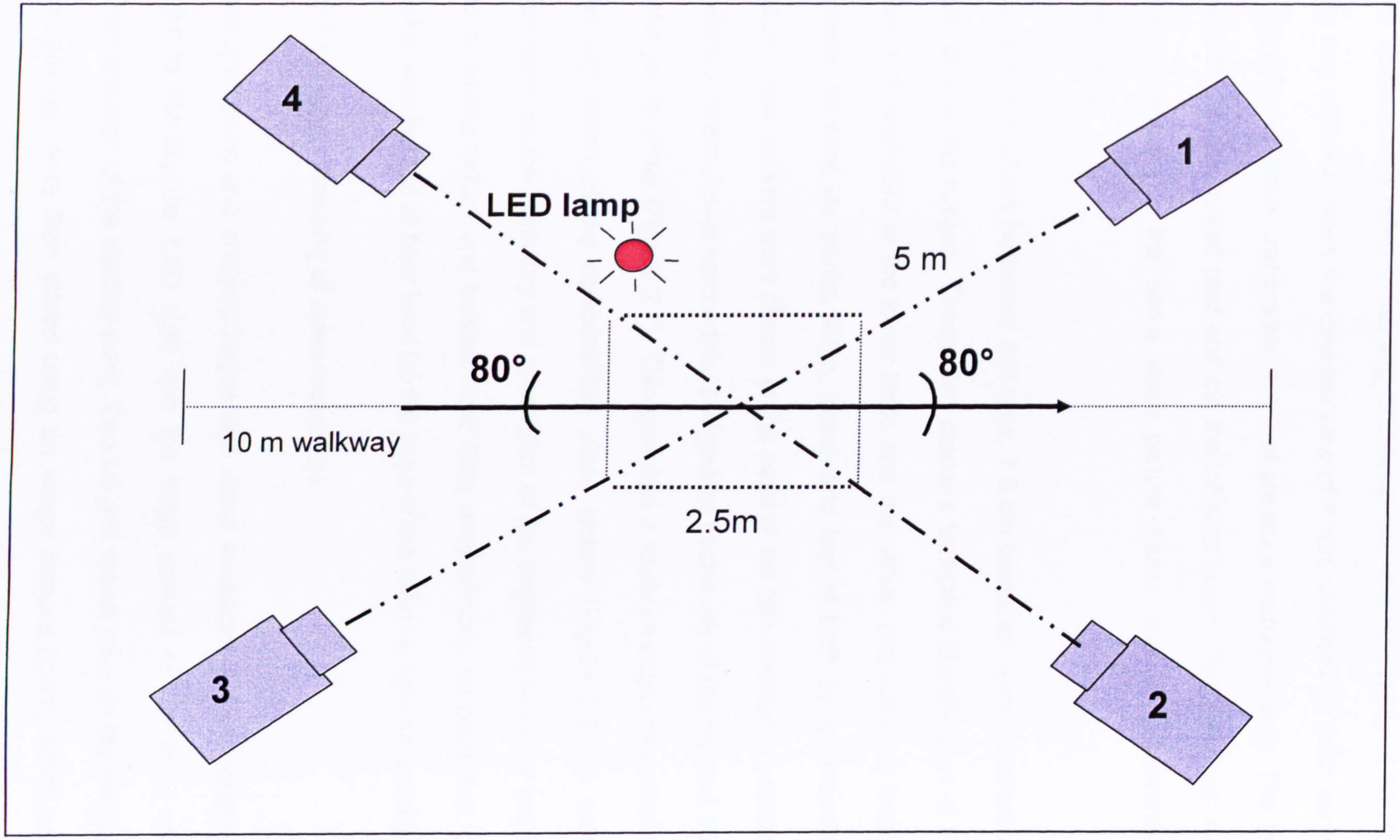


Figure 2.8 Schematic representation of the experimental and filming conditions used in the gait laboratory. The thick black arrow represents the direction of walking. In the middle, the dashed square shows the most visible area for each camera. Further details are given in the text.

relative to the calibration frame was also used to define the global co-ordinate system and the accuracy of subsequent measurements (Salo, 1999). The four camcorders were synchronised using a flashing LED-lamp set at a frequency of 50 Hz. The LED-lamp was situated where the clearest view of it was obtained by each camcorders and by the infrared beam transmitter (for foot-pressure measurement). The lamp flashed when the subject walked past and cut the infrared beam. The light flash was 'seen' by all four cameras, in the same video picture frame, thereby synchronising all four camcorders.

Twelve skin markers (reflective ball type, 1.5 cm diameter) were attached with double-sided tape to the subject. These skin markers facilitated identification of the centre of rotation of each joint of the lower limbs and the pelvis, and acted as local co-ordinate systems, defining the pelvis, thigh, shank and foot of both limbs in terms of position vectors. Skin markers were placed at the head of the fifth metatarsal, calcaneus, lateral malleolus, lateral femur epicondyle, the greater trochanter of the hip and the lateral line of the pelvic girdle (Figure 2.7). This provided a fourteen-segment performance model after digitisation of the computerised video picture (Figure 2.9). In order to obtain information on the trajectory and orientation of the segments in space (explained later), and to enable within- and between-test data comparisons, an additional 'control point' marker was located at floor level (at the base of the flashing light assembly).

2.5.2.1 Data processing of video recordings

Data processing and analysis began with visual assessment of videotape playback, in order to identify the LED light and the initial contact of the foot, which denoted synchronication of the starting point. Two full gait cycles (one on the left leg and one on the right leg) were then stored using an image capture board, which transferred the videotape images to a computer hard disk prior to examining body coordinates (digitising).

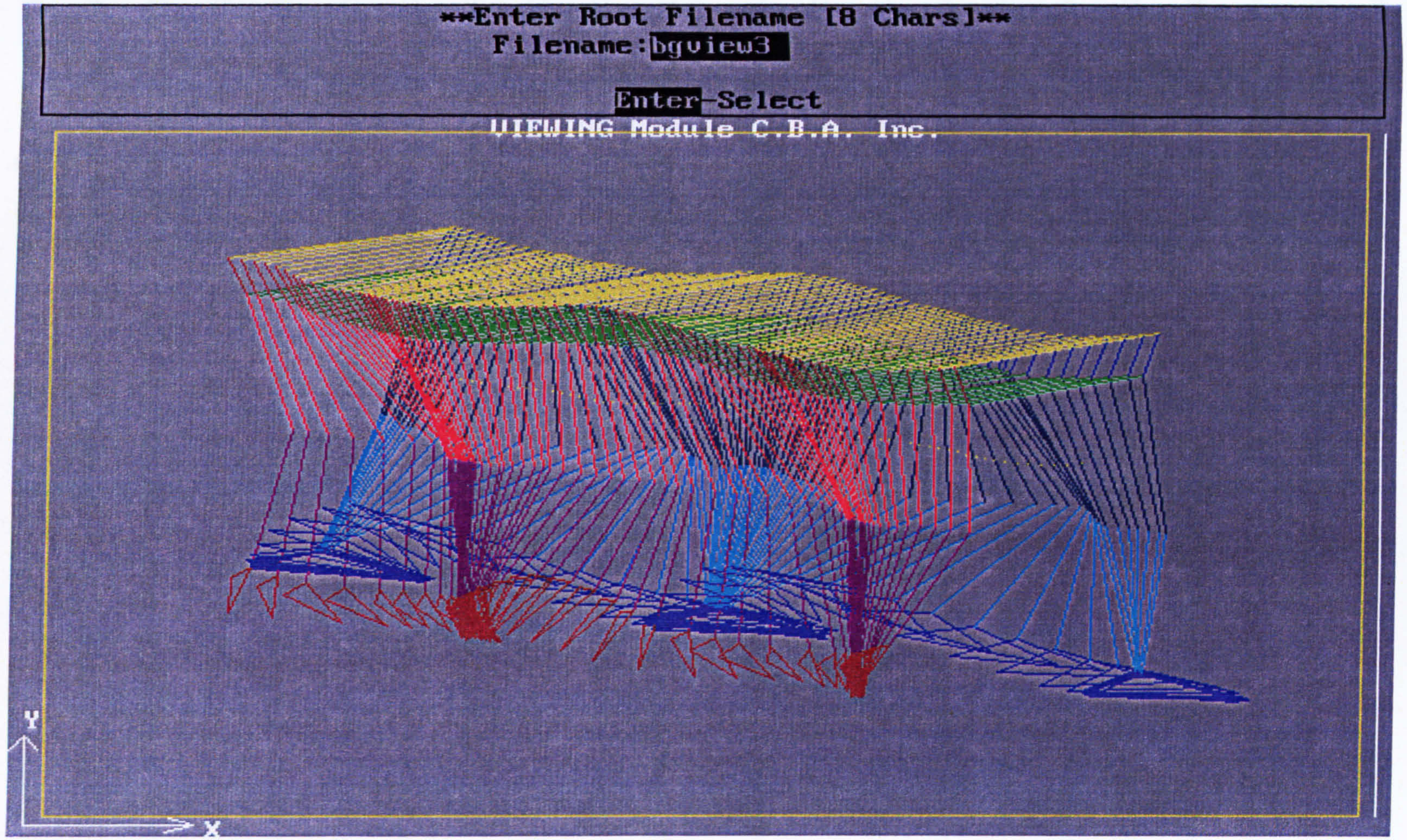


Figure 2.9 Segmental model constructed with two feet, two shank and two thigh segments and the pelvic square by APAS™ software. Each colour specified different segments; blue represents the left leg, red represents the right leg, and the yellow-green represents the pelvic square.

Digitising was initially carried out using the computer running Ariel Performance Analysis System (APAS™) software in the gait laboratory. However, this proved to be impractical, due to the large amounts of data involved and the slow CPU clock speed of the computer in the actively used gait laboratory. In order to enable digitising with a remote computer with higher specification, data files were transferred from the hard disk of the laboratory computer using portable data storage devices. Video graphic files were compressed using WINZIP™ and then copied via parallel port connections to external Iomega ZIP™/JAZ™ disks, or external Iomega DITTO™ tape format, and subsequently transported to the remote computer hard disk. The Iomega JAZ™ system provides sustained data transfer (read/write) rates up to 5.4 MB per second, onto 1 GB capacity disks, and proved to be the most efficient method. By this means, video data compression and transfer routines for each subject were achieved in approximately 50 minutes. A modification of this procedure was used for storing and archiving data.

The author digitised four view sequences from each trial using APAS™. Digitising commenced at the beginning of the left leg gait cycle (initial contact) and continued to the end of the second initial contact of the right leg. The resolution of the video digitising screen was set to 800 x 600 pixels. Occasionally, some body parts were temporarily obscured from one or two camera views (usually the ankle and knee of the contralateral lower leg, and part of the pelvis of the leading leg). In these instances, the locations of the joint centres were estimated as accurately as possible. Each marker point was highlighted on screen (when digitising) with a cursor ('mouse' operated) and stored on the hard drive of the computer. The data made available for further analysis were acquired from two full gait cycles (from the initial contact to the next initial contact) for the left and right legs.

2.5.2.2 Transformation of co-ordinate system

APAS™ captured the motion of the 12 markers attached to subjects' lower limbs and the additional 'control point' located on the laboratory floor at 50 Hz sampling frequency. The nine-marker calibration frame of a MACREFLEX™ motion analysis system (190cm x 100cm x 100cm, length, height and width, respectively), which included the same additional 'control point', was also used to calibrate the analysed volume. The location of the frame was determined at the middle of the recorded walkway. This defined the position of the global co-ordinate system within the field-of-view of each camera. The global co-ordinate system described the absolute position of the segments in space (Wu, 1995a). In order to avoid variation in results due to the calibration procedures, the calibration information was transformed for every digitised file (in each camera view).

Each data set with respective views (two-dimensional, 2-D, camera images) and calibration information were then transformed to give the 3-D co-ordinates of each marker, using the Direct Linear Transformation (DLT) and zero factor quintic splines algorithms (Woltring, 1984). These DLT parameters define, for example, the position from the camera lens to each marker and allow the reconstruction of the 3-D marker co-ordinates from the 2-D camera images. Once the DLT parameters were established for each camera view, the unknown movement space co-ordinates (x,y,z) of the markers were then reconstructed using the DLT parameters and the calibration image co-ordinates (x,y) for each camera. After the markers were identified in 3-D space, the data calculation was carried out using the generalised cross-validated quintic splines (Woltring, 1984; Koff, 1995).

The marker configuration was fitted to a mathematical model within APAS™ software, which enabled calculation of the 3-D co-ordinates of the markers, where the x-axis is pointed in the horizontal line of progression, the y-axis is pointed in the vertical and upward direction and the z-axis is in a sideways direction from the left to right (Figure

2.10) (Wu and Cavanagh, 1995). The same set of ground reference axes are used throughout the thesis, with the x-axis aligned with length of the laboratory. Thus, the x-axis lay in the direction of travel for the studies of subjects' walking, and measurements were obtained in the anterior-posterior direction. This is in contrast to the balance studies, where the z-axis was used as the direction for the anterior-posterior reference.

Kinematic analysis of human movement (for example, to calculate the joint angles) requires knowledge of the orientations of the segments relative to each other (Wu, 1995b). Thus, a local reference system must be defined relative to each segment. As such a local system is fixed to the segment, it is moving relative to the Earth (Wu, 1995a). Here, eight local reference systems were defined for each segment: the foot, shank, thigh and pelvis, on the affected and unaffected leg. The position and orientation of each of these co-ordinate systems were defined by at least three landmarks (Winter, 1990). The linear displacement and velocity of each marker point, and angular displacement and velocity of the joints and segments were analysed using APAS™ software routines (described later).

'Linear displacement' describes the translational component of the motion of a body segment moving in space, and can be represented either in the global or body-fixed reference frame, to define the absolute or the relative translation, respectively. 'Linear velocity' is the rate of change of the translational displacement (Winter, 1990; Wu, 1995a). 'Angular displacement' describes the rotational component of the motion of a body segment moving in space. When angular displacement is represented in the global reference frame, it is termed the segmental angular displacement, because it describes the absolute angular motion of the segment with respect to the global reference system (the angle of the segment with the vertical). However, when angular displacement is represented in the body-fixed reference frame of the adjacent body segment (e.g. the distal segment), it is often referred to as the joint angular

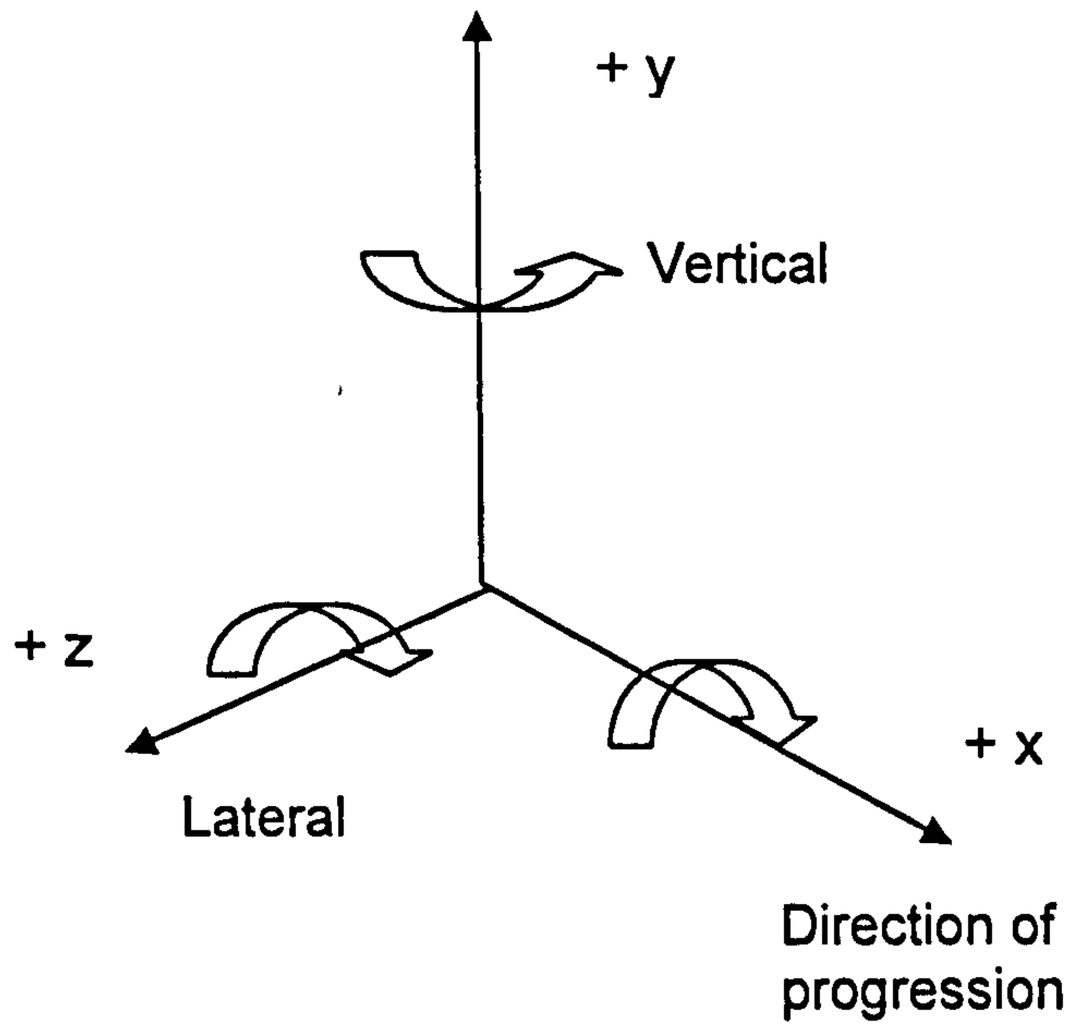


Figure 2.10 Absolute spatial coordinate system used in all data analyses. The directions of the x-, y-, and z-axes indicated were chosen so that (in 3-D studies) x and y lay in the saggital plane.

displacement, because it describes the relative angular motion of the segment with respect to another. 'Angular velocity' is the rate of change of rotational displacement (the first derivative of angular displacement) (Wu, 1995a).

In studies of human gait kinematics, there is no consensus as to which reference frame best defines the kinematic variables. In general, the components of the segmental and joint angular displacement vectors are not identical as described above. However, segmental angular displacement can be determined from the joint angular displacement and *vice versa*, providing that the relationship between the global and body-fixed reference frames is known (Wu, 1995a). At the start of the present studies, it was unknown which of the calculation methods would provide the most accurate and reliable data; consequently both the above approaches for representing kinematic variables were used in the reliability test.

2.5.3 *Accuracy of gait performance*

A separate study was performed to clarify which method for digitising the markers was most accurate for converting of the position of the lower limb joints from the video picture to the 3-D co-ordinates. One method involved manual tracking of each frame. Although this approach was time consuming it was less sensitive to errors from reflected light. An alternative, semi-automatic method was also possible using APAS™ software, providing that the tracked markers could be clearly seen in the video image. However, this method was found to be very sensitive to lighting errors. A light can be reflected from the floor, or from around the gait laboratory, causing bright areas in the image. In this case, the APAS™ software tools could erroneously track this reflected light as a marker point.

During the early stages of the project, the video recorded gait trial of a single subject was randomly selected from a group that had been already tested. The subject was a 64-year old male, with left side hemiparesis, who had had a stroke four months before

recruitment to the studies. One gait cycle recorded from this subject was re-digitised sixteen times on separate occasions. Digitisation was performed manually a total of eight times following anatomical joint centres at the fifth metatarsal, the calcaneus, ankle joint centre (subtalar joint), knee and hip joints centres, and the pelvic line. Digitisation was also performed eight times following reflective markers with the semi-automatic method. The markers attached to the patient's body were used to build a segmental model constructed with the two feet, two shanks, two thigh segments and the pelvic square (section number). The pelvic square was constructed by connecting the two hip and pelvic markers. The segmental model used was illustrated in Figure 2.9.

2.5.3.1 Data analysis of accuracy measurements

Effect on co-ordinates

The raw 3-D co-ordinates (x, y and z) were calculated as described earlier (section 2.5.2.). Linear displacement data for the sixteen repeated digitised values in one gait cycle were calculated separately for twelve body landmarks and for each co-ordinate of the segmental model. One gait cycle resulted in 105 fields of digitising (a field is a single image on the computer screen) in x, y and z-directions. Smoothed data were filtered with a 4^{th} order recursive Butterworth filter (6 Hz cut-off frequency). Re-digitised data values were then evaluated using statistical methods within SPSS™ software (Version 8.0, SPSS Incorporated). One-way ANOVA was used to indicate which method for digitising the markers was more accurate (Gresham *et al.*, 1995); further data analysis of the 3-D markers involved calculation of the root mean square error (RMSE) of the eight repeated digitisations. This procedure provided a measure of stability by indicating the level of variability over the total number of separate digitisations from the proximal to distal joints.

$$\sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(\hat{x}_i - x_i)^2}$$

n = number of repeated digitizations

x = number of video images from the heelstride to the next heelstride with same leg

High RMSE values indicate poor repeatability and the potential for difficulty reproducing the same motion. Conversely, lower RMSE values suggest a good level of stability (section 2.6).

Effect on variable calculations

In order to establish the accuracy of the variables, the co-ordinates (x, y and z) were also used to calculate linear and angular displacements and velocities from lower limb joints (using the body-fixed reference frame) and segments (using the global reference frame). This was carried out for 3-D movement of 3 joints (ankle, knee and hip) and 4 segments (foot, shank, thigh and pelvic) from both legs. The variables calculated are illustrated in Figure 2.11. These are standard and established parameters used to describe human gait performance (Winter, 1990; Winter, 1991a); values were calculated by APAS™ and exported to Microsoft WORD™ (Version 7) and EXCEL™ (Version 7) for Windows 95™. Further data manipulation and analysis were carried out using MATLAB™ (Version 5). The average and SD of all data sets were calculated separately. Further data analysis of the 3-D markers involved calculation of the root mean square error (RMSE) of the eight repeated digitisations, which, as indicated earlier, gives a measure of stability in relation to variability over the total number of separate digitisations from the proximal to distal joints.

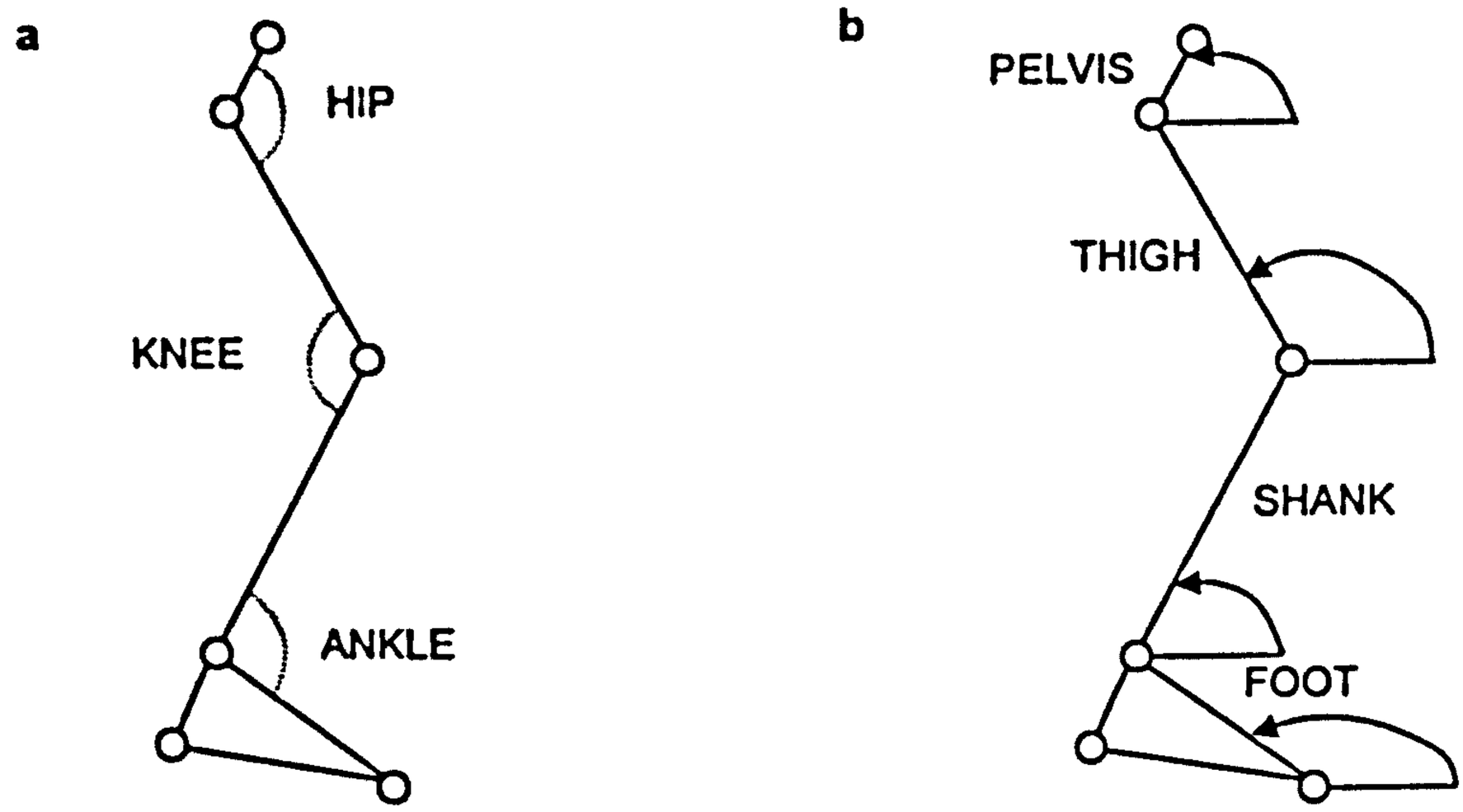
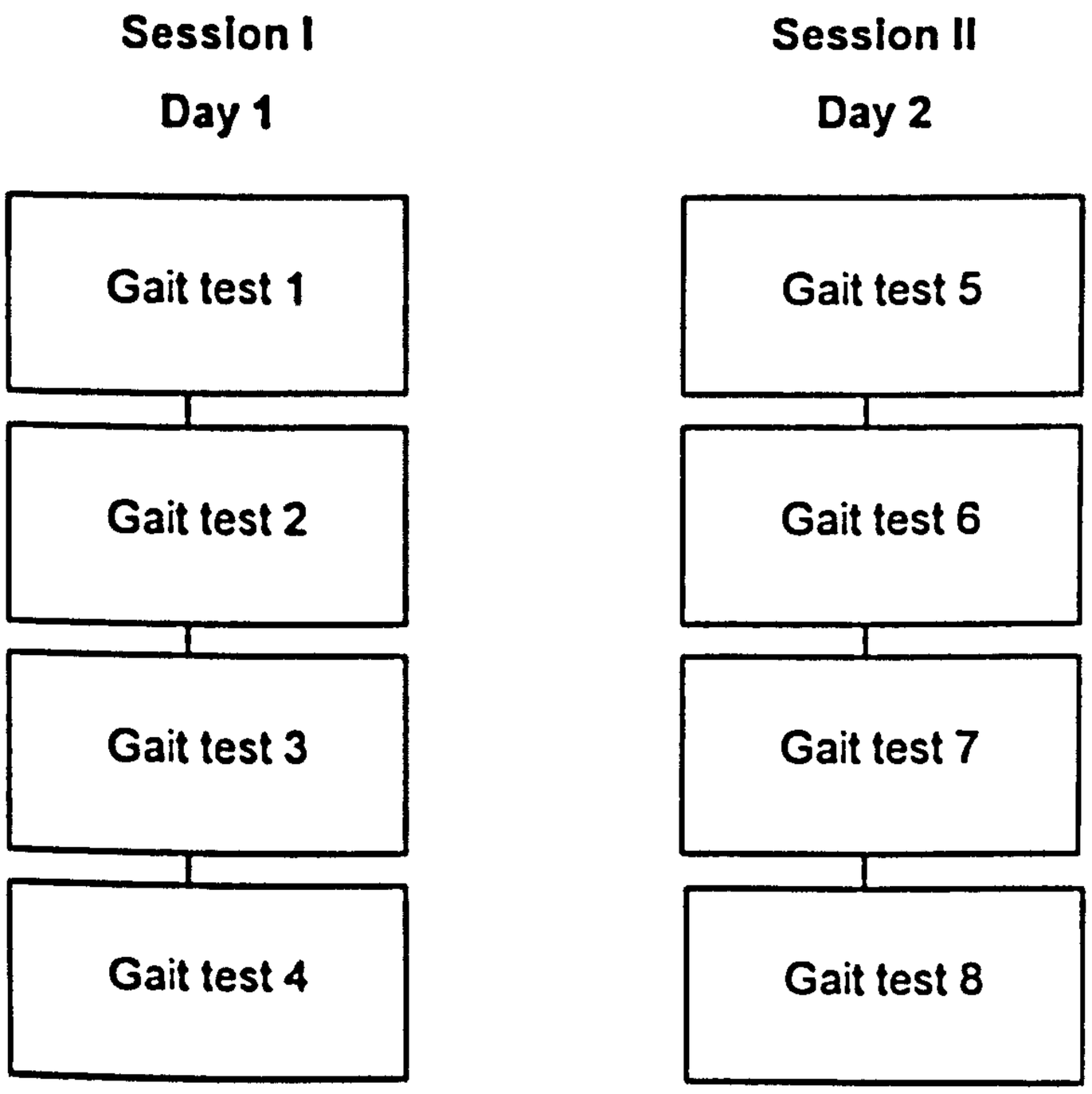


Figure 2.11 Kinematic variables used to assess the gait cycle. In (a) the angular displacement and velocity of ankle, knee and hip joints represented within the body-fixed reference frame is illustrated; (b) depicts the angular displacement and velocity of the foot, shank, thigh and pelvic segments with respect to the global frame of reference.

2.5.4 *Reliability and repeatability of gait measurements*

As there have been no detailed reports published on the reliability of the methods used here for analysing stroke patients' gait, it was important to determine how subjects' gait could vary both between different trials during the one-day testing session, and between two tests carried out on different days. Early in the main study phase, one subject was randomly selected from those who had already completed the tests, and used for a testing trial to evaluate the reliability and repeatability of gait measurement within and between testing days. The subject was a seventy-year-old male who had been diagnosed as having a right side hemiparesis seven months before the study. He used a walking stick in his left hand and wore a DAFO on his right foot. The subject was tested when walking on the 10-metre walkway as described earlier. However, in this case, the test was repeated four times in succession, with a 30-minute rest after each test; the same procedures were repeated one week later. Thus, data was obtained for a total of eight tests (Table 2.6).

Table 2.6 Testing design used to assess reliability of gait performance. Data collected from session I were used to assess repeatability within tests during a single day. Data from sessions I and II were used to assess repeatability carried out on different days.



2.5.4.1 Data analysis of reliability measurements

Raw linear displacement values were calculated separately for all 12-body landmarks in 55 fields of digitising and in the x, y and z-directions. In addition, smoothed data were filtered with a 4th order recursive Butterworth filter (6 Hz cut-off frequency). Linear displacement was calculated for smoothed 3-D co-ordinates from each body landmark to specify the position of the landmark, and the linear velocity of the markers was used to define the rate of changes in displacement for each repeated test on Day I and Day II. In addition, angular displacement and velocity were calculated from ankle, knee and hip joints both on the affected and unaffected sides. The final parameter estimates obtained were the foot, shank, thigh and pelvic segmental angular displacements and velocities from both legs. All kinematic parameters were normalised to a percentage of the duration of one gait cycle (100 % gait cycle). All variables were reported using APAS™ software, and exported to MATLAB™ as described earlier.

2.5.5 *Additional data analysis during main phase*

In order to enable simultaneous comparison of the subjects' affected and unaffected limb motions, data from two full gait cycles for both left and right legs were assessed. Four videotapes per trial (12 tapes per subject) were digitised during the main phase studies. It is notable that as only one operator (the author) was involved with this work, the digitising proved to be time-consuming. Thus, for each subject approximately 150 hours of digitising were required. A DLT algorithm was then used to reconstruct 3-D co-ordinates of the model from digitisation of the four views. The 3-D co-ordinates (x, y and z) were calculated for each landmark in the model (section 2.5.3.1) and the Cartesian co-ordinate system was used to describe the position and orientation of the lower extremity rigid body segments (Winter, 1991b). As the preliminary studies provided acceptable reliability results in the saggital plane, 2-dimensional analysis on this plane was used in the main phase of the analysis. All variables calculations were carried out

using APAS™ software with further data analyses with EXCEL™, MATLAB™ and PRISM™.

As described earlier (section 1.5), the magnitude of joint motion is specified as an independent item of information during the stance and swing phases. Defining motion occurring in each gait phase provides an interpretation of joint function that can delineate inappropriate aspects of gait magnitude and timing as minimum and maximum values (Morris, 1973; Winter, 1974; Apkarian *et al.*, 1989; Bartlett, 1997a). Here, the minimum value of thigh velocity was identified at the mid stance phase, to specify stability of the more proximal joints (De Quervain *et al.*, 1996). At the end of stance (push-off) phase, the minimum value of the thigh displacement and minimum value of the foot velocity were established to define flexibility and control of lower limb joints when the directions of joint movement changes (De Quervain *et al.*, 1996; Enoka, 2002). The minimum foot velocity is achieved during late stance and early swing phases, which is probably due to difficulties encountered by severely disabled walkers when releasing the foot from the floor. The minimum values from the segmental displacement and velocity of the foot and shank motions, including maximum thigh velocity, were measured at the early swing phase (toe-off), which is associated with the large ankle plantarflexion and knee extension (Lehmann *et al.*, 1987; De Quervain *et al.*, 1996; Olney and Richards, 1996). The maximum values of the foot and shank velocity were determined in the middle of the swing phase, which is related to large ankle and knee flexion (Wooley, 2001; Lamontagne *et al.*, 2002). The stance and the end of the stance phases, and the early and middle of the swing phases were deemed as reliable criteria for assessment of the stroke subjects, as these components of the gait cycle are believed to represent important reference points during the dynamic control of joint motions during walking (De Quervain *et al.*, 1996; Olney and Richards, 1996; Lamontagne *et al.*, 2001; Wooley, 2001) and therefore had potential to separate the putative effects of splints from shoes.

In addition, spatio-temporal stride parameters and gait velocity were derived from kinematic data calculated from the entire duration of the recording period. Data from joint motions were changed to Microsoft DOS™/Windows™ format. Data manipulation and further analyses were carried out using MATLAB™. All gait data were estimated manually from the linear displacement data on the computer screen (heel and toe markers) from heel strike (initial contact) to push-off, and from push-off to the end of the swing phase (next heel strike) to delineate one stride, and then normalised as a percentage of the duration of one gait cycle (from heel-strike to the next heel-strike as a 100 % gait cycle, Figure 1.1). For all tests, these procedures were carried out on data collected from both legs. The duration of a single gait cycle was determined from the time interval between two consecutive heel strikes of the same foot (for the left side) and two consecutive instants of toe-off (for the right side). The stride length was calculated from the trajectory of the heel marker during one gait cycle. The affected leg's step length was defined as the distance between the heel marker at heel strike and toe-off positions. The duration of the stance phase was derived from the time between heel strike and toe-off on the same side; the duration of the single stance phase was assessed from the time between the heel strike and that on the opposite leg. All temporal stride parameters were also calculated as a percentage of the duration of one gait cycle and all spatial stride parameters as a percentage of stride length. There was some variation in absolute velocity time. Consequently, all segmental kinematic parameters were normalised to 100% of the gait cycle.

All of the analysed spatio-temporal and kinematic results were saved and archived for the two groups (control and experimental), and for the three consecutive tests (tests I-III). The gait variable measurements determined from each stride of the affected and unaffected legs were retained separately for analysis. The results from the reliability tests presented earlier (section 2.5.4) indicated that measures of these variables yielded acceptable reliability and repeatability in the saggital plane. In addition, earlier reports of

gait assessment and clinical rehabilitation studies have shown that the effects of different experimental conditions on these variables can be determined (Burdett *et al.*, 1988; De Quervain *et al.*, 1996; Evans *et al.*, 1997).

2.6 Statistics

2.6.1 Randomisation

Randomisation of subjects' testing order was performed using STATMATE™ (Version 1.01, Graphpad Incorporated). Each subject was designated a number from 1 to 20 and this was entered (in ascending numerical order) onto the STATMATE™ data sheet. The software was then used to assign the numbers to (in this case) one of two groups, based on pseudo-random number algorithm procedures.

2.6.2 Distribution

The distribution of subjects' age, weight and height was tested using Dallal and Wilkinson approximation to Lilliefors' method within PRISM™ (Version 3.02, GraphPad Incorporated). The mean values for each factor (age, height and weight) were compared between groups using two-tailed unpaired *t*-tests.

2.6.3 Preliminary studies

2.6.3.1 Balance

Deviation of data from a Gaussian distribution was assessed using the Kolmogorov-Smimov test; the *p* value for normality was determined using the Dallal and Wilkinson approximation to Lilliefors' method. In general, it was found that data followed a normal distribution. For this reason, arithmetic mean and SD values are reported unless stated otherwise. Comparisons were made of balance test data collected both within- and between-testing sessions. In both situations the C.V. of the repeated measurements was used.

2.6.3.2 Gait - accuracy (effects on co-ordinate and variable calculations)

Determination of the accuracy of variable measurements was carried out for raw and filtered 3-D movement data for the six body markers' (foot, heel, ankle, knee, hip and pelvic) displacement and velocity for both legs. One gait cycle resulted in 105 fields of digitising (a field is a single image on the computer monitor screen) in x, y and z-directions. The mean and SD of all data sets were calculated separately. One-way analysis of variance (ANOVA) was used to indicate which method of digitising the markers was more accurate ($p < 0.05$). Further data analysis of the 3-D markers involved calculation of the root mean square error (RMSE) for effects on co-ordinate and variable calculations, for the 8 repeated digitisations. These procedures provide a measure of stability by indicating the level of variability over the total number of separate digitisations from the proximal to distal markers (Gresham *et al.*, 1995; Allard *et al.*, 1996).

2.6.3.3 Gait - performance reliability

The reliability of subjects' gait was assessed in order to determine inherent differences occurring between different trials during the one-day testing session, and between two tests carried out on different days. Reliability assessments were made for 3-D movement of 3 joints (ankle, knee and hip) and 4 segments (foot, shank, thigh and pelvic) for both legs; data were obtained for a total of 8 tests. The C.V. for each of the body landmarks and angular/segmental displacements and velocities data series were calculated independently for each of the data sets. All variables were calculated as a percentage of the duration of one gait cycle.

2.6.4 Main phase - Balance data

Differences between groups were accessed using two-tailed unpaired *t*-tests or ordinary/repeated measures ANOVA or multiple analysis of variance (MANOVA) with appropriate post-tests. These analyses were done using PRISM™ or SPSS™.

2.6.5 Main phase - Gait data

All spatio-temporal and kinematic variables were normalised to a percentage of the duration of one gait cycle (100%). Differences between groups were assessed using ordinary measures ANOVA with Bonferroni's multiple comparison post-test. Within the experimental group, experimental condition comparisons (shoes and DAFO) were carried out (after Ryan-Joiner normality tests) using paired *t*-tests or Wilkoxon signed rank tests, as appropriate. Bivariate correlations of gait and balance data were performed with 2-tailed Pearson's analysis. An improvement is indicated when the values came closer to normal reference values.

The functional gains of the subjects over time were analysed using standard repeated-measures procedures. Data for functional assessment scales (Nottingham Extended ADL and Rivermead Motor Assessment) were obtained using ordinal level of measures and are reported as the mean and range. Statistical comparisons between the control and experimental groups for each ADL scale were carried out using the Mann-Whitney U-test. The subjects' own opinions of splint usage were reported with a non-validated scale numbered from 0 - 4 (Appendix III) and descriptive information. For all statistical comparisons, the *p* value for significance was taken as 0.05. All data analyses were carried out using APAS™ software, and with EXCEL™, MATLAB™, PRISM™ and MINITAB™ as described earlier.

3 RESULTS AND DISCUSSION

3.1 Preliminary studies

This section summarises the results of preliminary investigations that used both healthy subjects and stroke patients. The preliminary work consisted of a pilot study, which examined the assessment methods for subject recruitment (Appendix I), as well as the design, manufacture and provision of orthoses (Appendix II). Preliminary studies were also done to assess the accuracy and reliability of the methods used to measure subjects' balance and gait, and to ensure that data compatible with earlier published reports could be obtained. These measurements were carried out on a routine basis throughout the research project; some of the results are presented here. It is emphasised that when testing older subjects and the severely disabled, great care has to be taken when choosing subjects for study in relation to the type of clinical intervention, the measurement techniques used and the duration of the testing sessions. Thus, preliminary studies were essential in order to be fully confident that all of the procedures used during the research were reliable for clinical purposes. The section concludes with a discussion of the main findings of the preliminary work, with emphasis on appropriate modifications implemented during the main studies.

3.1.1 Results

3.1.1.1 Balance test reliability

The reliability of balance measurements collected using the force platform apparatus was monitored by regular assessment of stroke and healthy subjects' ability to maintain an upright standing position. The co-ordinates of the CoP (Az = a-p, Ax = lat) and shear forces (Fz = a-p, Fx = lat), recorded with subjects' eyes-open and eyes-closed, were used to assess control of static standing (section 2.5). Comparisons were made of balance test data collected both within- and between-testing sessions.

For testing of within-session reliability, eight separate trials were performed. Data for individual balance characteristics were firstly recorded from 4 repeated trials. After the subjects rested briefly, the measurements were repeated 4 further times. The C.V.s of the repeated measurements of the balance variable estimates were calculated to determine reliability of the measures. Representative data are shown in Table 3.1.

Table 3.1 Within-session reliability. C.V. (%) of CoP (sway index) and shear forces (mean, SD and slope) measurements calculated in a-p and lateral directions with subjects' eyes-open and eyes-closed. Data were determined from a total of 8 measurements recorded during two sessions on the same day with 4 subjects.

Parameter	*Direction*	*Eyes-open* C.V. (%)	*Eyes-closed* C.V. (%)
CoP	a-p	7.73	5.84
	lateral	4.83	5.84
F(mean)	a-p	3.59	4.50
	lateral	4.46	4.47
F(SD)	a-p	1.94	2.03
	lateral	3.17	2.68
F(slope)	a-p	1.83	2.65
	lateral	5.32	2.13

The finding that all of the C.V. values determined were < 10 % and most < 5 % indicated good reliability for parameter estimates obtained during recording sessions conducted on the same day.

For determination of between-session reliability, the balance measurements (CoP and shear force) were repeated at two-weekly intervals during the first 6 weeks, and then at weeks 12 and 14. Data manipulation and parameter calculations were performed as described earlier (section 2.5).

Table 3.2 Between-session reliability. Mean values of CoP co-ordinates Az and Ax (cm) and shear forces Fx and Fz (Hz) measurements on six occasions and C.V. (%) values of between-tests reliability assessments (comprising 6 measurements over a 14 weeks period).

Testing time	Fx	Fz	Az	Ax
Baseline	0.64	0.64	5.86	3.72
2 weeks	0.51	0.64	4.62	1.91
4 weeks	0.69	0.73	2.89	4.03
6 weeks	0.69	0.64	3.11	4.49
12 weeks	0.75	0.67	4.28	4.04
14 weeks	0.67	0.47	2.60	2.34
C.V. (%)	**1.15**	**1.24**	**17.88**	**14.91**

In the between-session reliability assessments, the C.V.s of the parameter estimates were also low, at < 10 % for Fx and Fz, and < 20 % for Az and Ax, and indicated acceptable reliability. Thus, the values of > 10 % were considered reasonable for recordings obtained between measurements taken over a three months period. Representative data are shown in Table 3.2. These data are compatible with earlier reports of reliability assessments for balance characteristics in healthy subjects using similar methods (Geurts *et al.*, 1993; Burnfield *et al.*, 2000). The clear difference in variation between the estimates for Fx/ Fz and Az/ Ax was predictable, and is explained by force measures being more sensitive than CoP measures in discriminating the changes in steadiness, which resulted from alterations to the base of support (representing the vibration of the body during standing) in the stance position. These data therefore confirm and extend earlier findings (Liu and Lawson, 1995; McClenaghan

et al., 1995; Burnfield *et al.*, 2000). As these measurements were carried out on a routine basis throughout the entire duration of the main testing trials, the low variability indicated by the work validated the applicability of the methods for research purposes.

3.1.1.2 Accuracy of gait performance

Effects of repeated digitising on co-ordinates

A separate study was performed to determine the most suitable method for digitising the markers in relation to accuracy when assigning 3-D co-ordinates to the position of the lower limb joints in the video images. Two methods were assessed based on manual and semi-automatic approaches. The manual method involved assessing the tracking of each frame individually. The semi-automatic method used computer software that tracked markers in sequence, providing that they were visible within the video image and could be 'recognized' by the software. The raw and filtered 3-D co-ordinates (where x is horizontal forward, y is the vertical direction and z is the lateral direction) were calculated using procedures as described earlier (section 2.6.2.). Re-digitised data values were evaluated using the one-way ANOVA and appropriate post-tests were used to indicate which method for digitising the markers was more accurate; for presentation here, RMSE (%) of variation values are given, where higher values represent low (poorer) repeatability (section 2.6.3).

The results from repeated digitisation using the two methods (manual and semi-automatic) for each marker are presented in Table 3.3. The manual digitising method revealed higher % values compared to the semi-automatic method on 4 occasions for the left leg and 12 occasions for the right leg. The semi-automatic indicated higher % values for 14 assessments of the left leg and 6 of the right leg. These studies revealed that the values obtained using the manual method, were overall, clearly lower (and therefore more reliable) than those obtained via the semi-automatic method. The

Table 3.3 Effect of repeated digitisation on markers' linear displacement

		Digitising method			
Markers	**Axis**	**Manual (%)**	**Auto (%)**	**Manual (%)**	**Auto (%)**
		Left side		*Right side*	
Foot	x	7.83	7.72	11.41	9.23
	y	2.38	3.94	2.58	3.64
	z	5.53	6.89	6.97	7.45
Heel	x	12.40	10.54	10.96	9.02
	y	3.50	6.95	4.00	6.18
	z	7.78	11.69	7.80	6.89
Ankle	x	9.04	10.19	9.61	8.99
	y	4.05	9.48	4.33	4.37
	z	6.19	8.64	8.30	7.12
Knee	x	4.94	7.68	8.88	8.37
	y	4.30	4.36	6.21	4.77
	z	4.14	5.48	6.47	5.57
Hip	x	5.49	7.75	9.00	8.39
	y	3.35	4.35	4.41	4.23
	z	4.58	3.99	7.64	5.67
Pelvis	x	6.67	11.81	6.65	8.64
	y	4.54	4.50	4.12	3.93
	z	5.19	5.35	4.65	6.41

Digitisation of markers was undertaken using two different methods (manual and semi-automatic) in x, y and z directions. Separate determinations were made for the left and right side. Values are RMSE in %. For details, see text.

manual tracking method was therefore used routinely for all subsequent analysis of gait data and during the main phase of the research.

Effects of repeated digitising on variable calculations

In order to provide a measure of stability indicating the level of variability over the total number of separate digitisations from proximal to distal joints, the co-ordinates and selected variables were smoothed. Smoothed data were filtered with a 4^{th} order recursive Butterworth filter (6 Hz cut-off frequency). The linear displacement and velocity from each digitised body mark were determined by APAS™ software using established kinematic models. Further data analysis from 3-D markers involved calculation of the root mean square error (RMSE) of the eight repeated digitisations. This procedure provides a measure of stability by indicating the level of variability over the total number of separate digitisations from the proximal to distal joints. High RMSE values indicate poor repeatability and the potential for difficulty reproducing the same motion. Conversely, lower RMSE values suggest a good level of stability (section 2.6.3).

The mean deviations and (ranges) of RMSE determined for all joints were relatively low, at 2.98 % (9.57) and 2.41% (8.75), for linear displacement of the left and right leg, and 1.75 % (7.06) and 1.66 % (4.97) for velocity of the left and right leg, respectively. The lowest RMSE values in all directions for both legs were for the pelvic linear displacement motion, at 3.53 % (0.72). The highest values, 6.35 % (3.60), were obtained for the motions of the heel. The lowest RMSE for linear velocity values were evident with the ankle motions, at 3.93 % (1.79), and the highest occurred for the foot motions, 4.98 % (2.41). These data therefore did not reveal a clear pattern to suggest that certain points are more visible throughout two gait cycles. The maximum deviations were gained for the foot (y-direction of the left leg), heel (x-direction of the left leg) and ankle (x-direction of the right leg) points. It is notable that these points are obstructed for the longest time from different camera views by other body parts. Consequently, it is easy for the operator to lose track of these points and increase error. Table 3.4

summarises RMSE values (percentage) for the smoothed 3-D coordinates in the linear displacement and velocity assessments undertaken for both legs.

3.1.1.3 Reliability and repeatability of gait measurements

Gait performance reliability was also tested to assess how subjects' gait could vary between different tests during the one-day testing session, and between multiple trials carried out on different days. A subject with right side hemiparesis was selected at random from those who had already completed the main tests. The subject's kinematic gait parameters were tested when walking on a 10-metre walkway. The tests were repeated 4 times in succession with 30 minutes rest after each test; identical procedures were repeated 1 week later

In order to provide a thorough assessment of reliability and repeatability of kinematic variables, data for complete gait cycles (affected and unaffected leg) collected from each test were analysed. For each test, data values were calculated separately for 12 body landmarks in 51 analysed fields and in x-, y- and z-directions. The linear displacement and velocity of each landmark were investigated. The segmental displacement and velocity were analysed from foot, shank, thigh and pelvic segments. The angular displacement and velocity were calculated from the ankle, knee and hip joints. All variables were calculated with APAS software™. The C.V.s for each angular and segmental displacement and velocity data series were calculated independently for each of the re-digitised data sets. This information was used to indicate the reproducibility of the patient's gait performance and to indicate the most reliable method to assess joint motions from video-based movement analysis data collected from stroke subjects.

Table 3.4 Effect of repeated digitising on 3-D co-oordinate calculations

		Three-dimensional motion			
Markers	**Axis**	**Linear displacement**		**Linear velocity**	
		Left side	*Right side*	*Left side*	*Right side*
Foot	x	6.69	8.69	8.88	6.25
	y	1.50	1.49	2.65	2.44
	z	4.62	5.40	4.39	5.28
Heel	x	11.23	9.10	6.39	5.44
	y	2.42	2.11	2.18	3.18
	z	6.71	6.52	4.27	5.82
Ankle	x	7.70	10.22	4.97	6.60
	y	2.99	2.92	1.82	2.33
	z	4.97	7.01	3.31	4.54
Knee	x	1.98	5.85	2.77	7.00
	y	3.62	4.82	2.14	4.08
	z	2.27	5.07	4.89	3.24
Hip	x	2.91	6.53	3.34	7.30
	y	1.66	3.34	2.33	3.23
	z	2.24	6.37	5.00	6.63
Pelvis	x	4.29	4.28	3.81	6.15
	y	2.43	3.47	3.13	3.47
	z	3.05	3.65	4.60	3.38

Data are the RMSE (%) of mean linear displacement and velocity of the joint movements from the full gait cycle calculated for eight repeated digitisations for the left and right leg. For details, see text.

Linear displacement of landmarks

Linear displacement describes the translational component of the motion of a body landmark moving in space (Bartlett, 1997a). Examples of linear displacement data collected during test I and test II for the right ankle, knee and hip markers located on each leg are shown in Figures 3.1, 3.2 and 3.3, with average values from the four repeated trials in each test summarised ± 1 SD in x (antero-posterior), y (vertical) and z (lateral) directions.

As expected, the variability of the right ankle landmark linear displacement was lowest during stance phase when ground support limits joint motion, and highest during swing phase when ankle joint motion changes from extension to flexion. The single lowest variability of the right ankle landmark values recorded in the x-, y-, and z-directions were 43.4 mm, 0.63 mm and 2.45 mm, respectively. Thus, variability in the y direction was considerably lower than in the x- and z-directions. The variability between trials in the y-direction showed that approximately 80 % of the values had < 10 mm variation in a full gait cycle, which indicated good levels of reliability, and is consistent with limited earlier reports of kinematic measurement variability seen with healthy and disabled subjects (Wall and Crosbie, 1995; Salo, 1999; Romkes and Brunner, 2002).

The maximum deviation between the four trials revealed the existence of further variability differences between each landmark axis. The maximum deviation of the right ankle marker was 188.1 mm in the x-direction at late swing phase, just before the new heel strike. The maximum deviations in the y- and z-directions (18.25 mm and 33.25 mm) were clearly lower than those recorded in the x-direction. In contrast to the variability seen in the x-direction in late swing phase, the major variability evident in both y- and z-directions occurred during mid-swing phase (Figure 3.1).

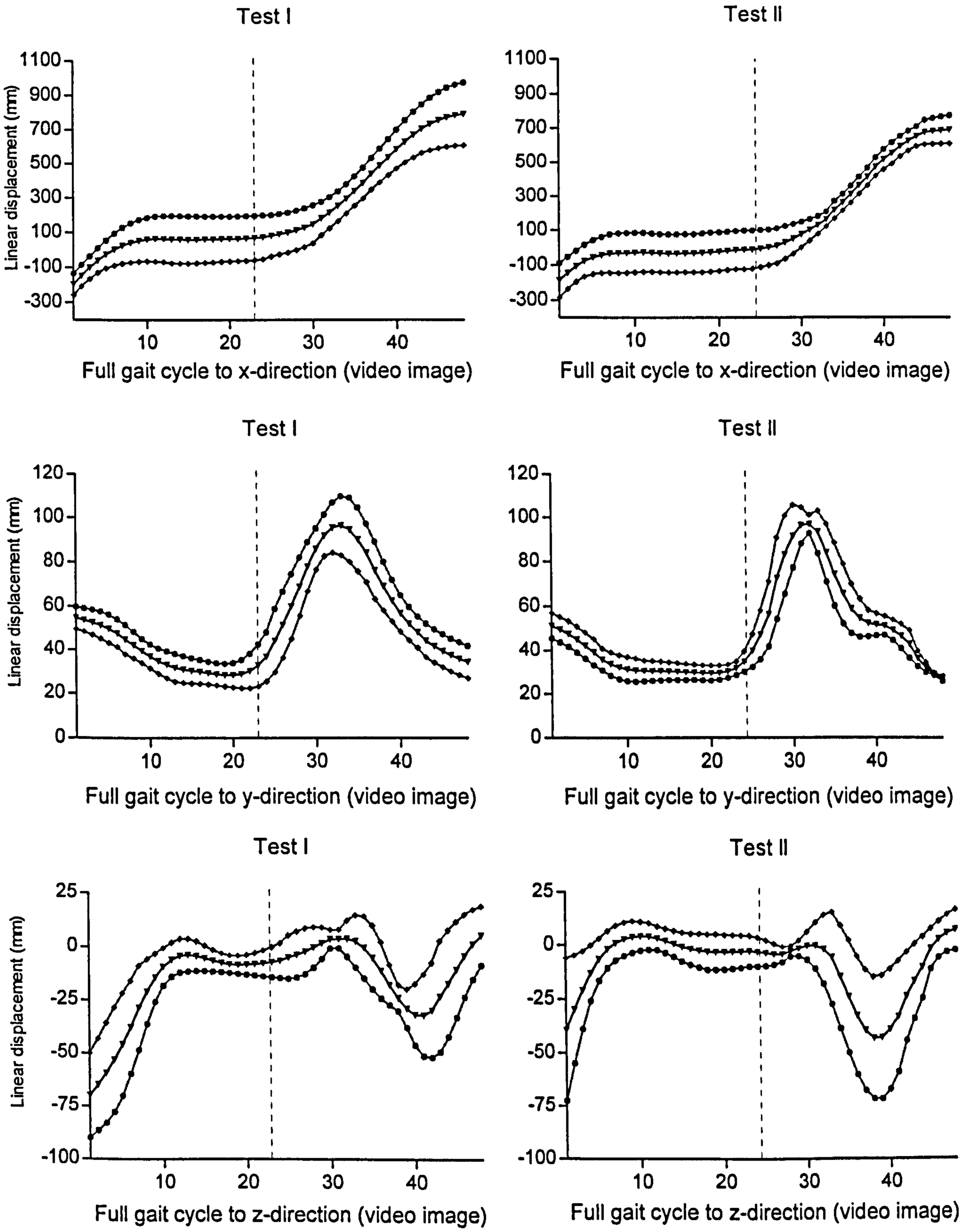


Figure 3.1 Linear displacement of right ankle marker: three-dimensional components. Representative data for deviation of linear displacement (right ankle marker) collected during tests I and test II. Data are the mean ± 1 SD from 4 repeated gait cycles. The dashed line on each graph separates stance phase (left of line) from swing phase (right of line). X-axis present digitised video images in full gait cycle (25 images/s). For details, see text.

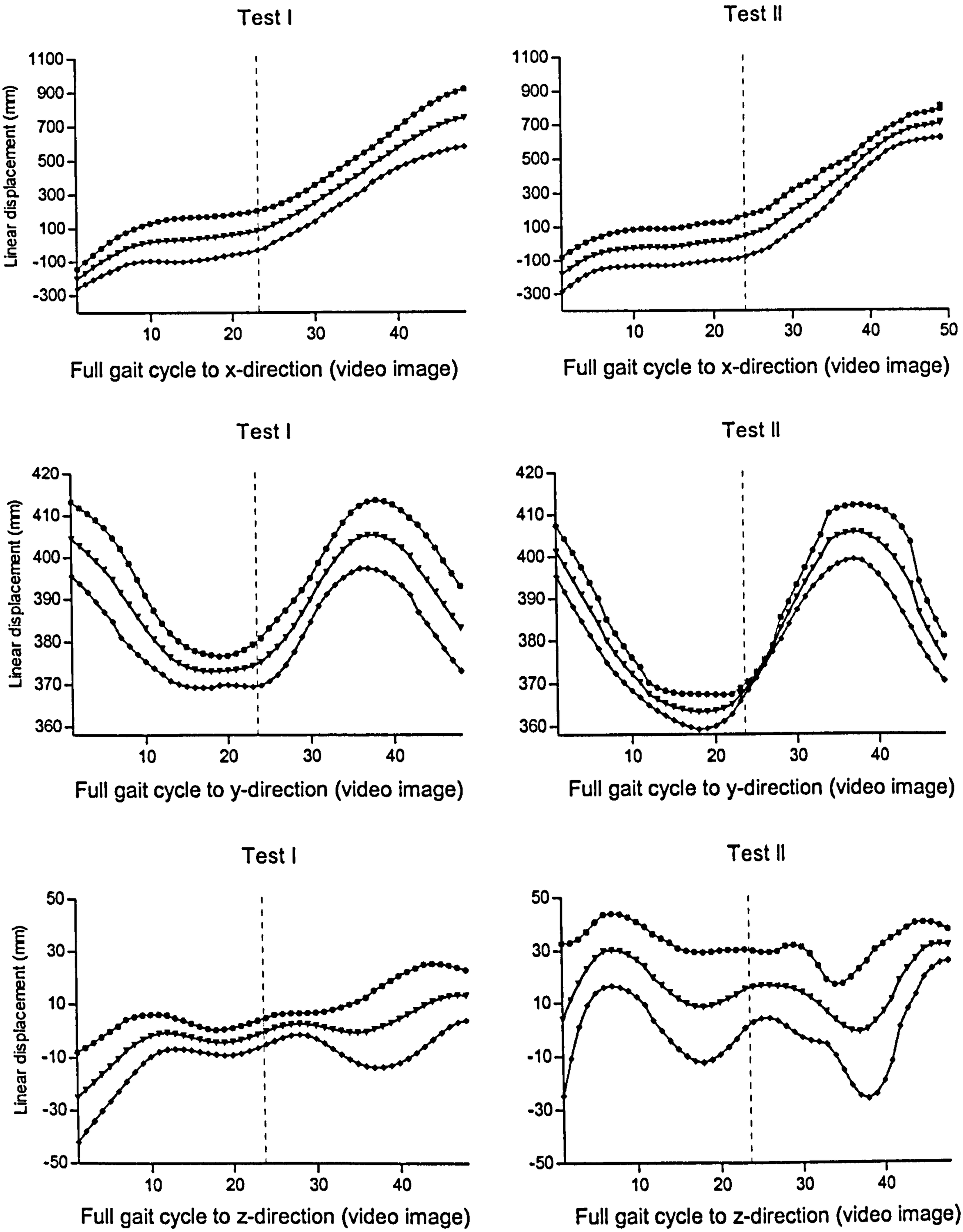


Figure 3.2 Linear displacement of right knee marker: three-dimensional components. Representative data for deviation of linear displacement (right knee marker) collected during tests I and test II. Data are the mean ± 1 SD from 4 repeated gait cycles. The dashed line on each graph separates stance phase (left of line) from swing phase (right of line). X-axis present digitised video images in full gait cycle (25 images/s). For details, see text.

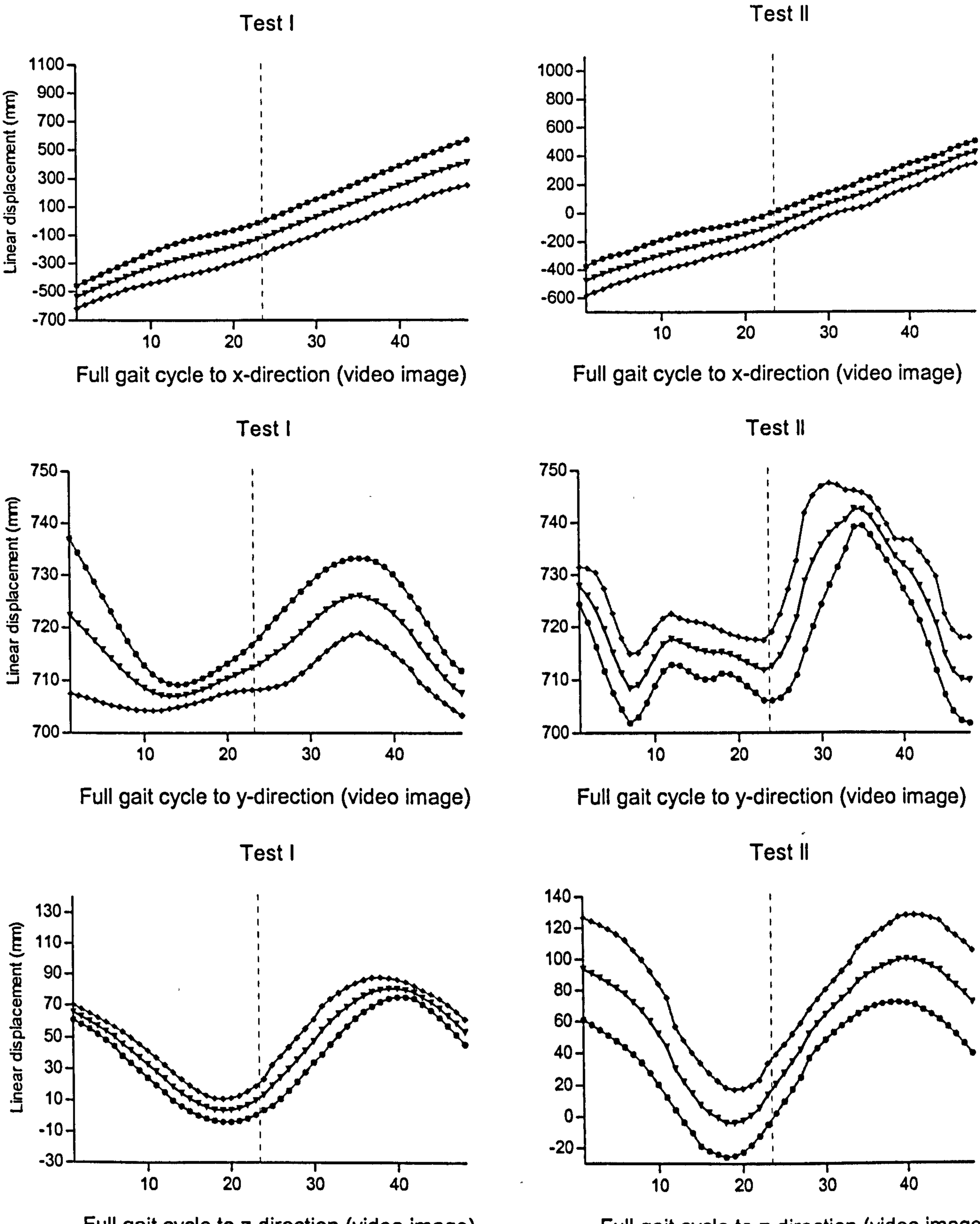


Figure 3.3 Linear displacement of right hip marker: three-dimensional components. Representative data for deviation of linear displacement (right hip marker) collected during tests I and test II. Data are the mean ± 1 SD from 4 repeated gait cycles. The dashed line on each graph separates stance phase (left of line) from swing phase (right of line). X-axis present digitised video images in full gait cycle (25 images/s). For details, see text.

Linear displacement estimates for the right knee landmark revealed that the maximum deviation (188.6 mm) also occurred in the x-direction during the second heel strike. The maximum deviations in the y- and z-directions (10.54 mm and 28.71 mm) were clearly low. The single lowest variability of the right knee landmark recorded in the x-, y-, and z-directions were 57.8 mm, 0.69 mm and 3.98 mm, respectively (Figure 3.2). Thus, variability in the y- and z-directions was considerably lower than in the x-direction. The variability between trials in the y-direction showed that approximately 95 % of the values had < 10 mm variation in a full gait cycle, which indicated particularly good levels of reliability (Romkes and Brunner, 2002).

Linear displacement determinations for variability of the right hip landmark indicated that the maximum deviation was 173.6 mm in the x-direction during the second heel strike. The maximum deviations in the y- and z-directions (14.76 mm and 34.24 mm) were considerably lower. The single lowest variability of the right hip landmark values recorded in the x-, y-, and z-directions were 72.19 mm, 2.01 mm and 4.17 mm, respectively (Figure 3.3). Thus, as was seen with the right ankle and knee markers, variability of the right hip landmark in the y direction was considerably lower than in the x- and z-directions. The variability between trials in the y-direction showed that approximately 80 % of the values had < 10 mm variation in full gait cycle, again suggesting good levels of reliability (Romkes and Brunner, 2002).

Data for the deviation of linear displacement calculations are summarised in Table 3.5. The C.V. values calculated for each of the landmarks during test I and test II revealed good overall reliability, especially for the y-component (vertical). In this direction, the clear majority of the landmarks (12) yielded C.V. values of < 6% and 3 less than 10 %. In contrast, there was much a larger variation in measurements collected in the x-direction.

Table 3.5 Reliability of repeated gait performance for landmarks calculated. Mean, minimum and maximum values are in millimeters and C.V. is in percentages. For details, see text.

Linear displacement values (mm) during one gait cycle					
	Right ankle marker			***Left ankle marker***	
X-direction	*Test I*	*Test II*	*X-direction*	*Test I*	*Test II*
Mean	125.87	86.55	Mean	90.51	93.60
Min	61.37	43.42	Min	46.72	38.76
Max	188.06	113.98	Max	114.40	122.18
C.V.	64.67	40.80	C.V.	27.19	35.44
Y-direction			*Y-direction*		
Mean	8.21	6.15	Mean	13.24	10.51
Min	5.04	0.63	Min	3.07	1.79
Max	15.06	18.25	Max	36.63	32.70
C.V.	5.56	7.36	C.V.	18.77	14.50
Z-direction			*Z-direction*		
Mean	12.25	12.71	Mean	12.84	11.59
Min	4.07	2.45	Min	6.44	2.37
Max	25.81	33.25	Max	17.94	29.71
C.V.	11.70	14.66	C.V.	6.91	11.85
	Right heel marker			***Left heel marker***	
X-direction	*Test I*	*Test II*	*X-direction*	*Test I*	*Test II*
Mean	127.52	89.05	Mean	84.28	60.23
Min	54.16	33.92	Min	11.10	17.70
Max	204.17	123.98	Max	235.73	131.08
C.V.	74.90	43.43	C.V.	108.47	47.02
Y-direction			*Y-direction*		
Mean	14.88	9.79	Mean	22.52	15.48
Min	3.98	1.82	Min	3.49	1.89
Max	36.58	27.95	Max	69.37	46.72
C.V.	13.28	12.89	C.V.	30.35	24.27
Z-direction			*Z-direction*		
Mean	18.47	15.18	Mean	20.84	13.35
Min	1.64	1.28	Min	3.40	3.34
Max	49.78	45.99	Max	34.13	33.56
C.V.	21.42	20.68	C.V.	108.47	47.02
	Right toe marker			***Left toe marker***	
X-direction	*Test I*	*Test II*	*X-direction*	*Test I*	*Test II*
Mean	130.04	84.72	Mean	132.06	98.40
Min	51.27	31.45	Min	73.37	37.70
Max	179.53	129.28	Max	175.09	144.45
C.V.	61.22	49.00	C.V.	57.68	43.17
Y-direction			*Y-direction*		
Mean	6.84	6.28	Mean	5.48	6.37
Min	1.12	1.17	Min	0.84	0.98
Max	14.58	15.12	Max	13.77	12.90
C.V.	7.32	5.81	C.V.	6.38	4.81
Z-direction			*Z-direction*		
Mean	18.31	14.92	Mean	16.89	13.97
Min	1.82	1.27	Min	5.71	4.50
Max	48.46	41.49	Max	37.34	46.25
C.V.	19.45	20.28	C.V.	14.51	16.95

Linear displacement values (mm) during one gait cycle

	Right knee marker			***Left knee marker***	
X-direction	*Test I*	*Test II*	*X-direction*	*Test I*	*Test II*
Mean	123.78	99.06	Mean	129.09	88.30
Min	57.80	65.14	Min	81.76	40.05
Max	188.61	121.08	Max	165.37	118.56
C.V.	58.01	30.73	C.V.	51.30	34.44
Y-direction			*Y-direction*		
Mean	7.20	4.71	Mean	5.81	4.08
Min	3.44	0.69	Min	0.51	1.34
Max	10.54	10.21	Max	10.94	9.33
C.V.	4.19	4.19	C.V.	4.37	2.81
Z-direction			*Z-direction*		
Mean	9.48	15.46	Mean	12.21	17.09
Min	3.98	4.98	Min	0.18	7.19
Max	16.96	28.71	Max	25.77	24.81
C.V.	58.01	30.73	C.V.	10.11	8.74
	Right hip marker			***Left hip marker***	
X-direction	*Test I*	*Test II*	*X-direction*	*Test I*	*Test II*
Mean	127.11	91.23	Mean	124.59	89.48
Min	78.76	72.19	Min	81.71	68.96
Max	173.60	110.94	Max	160.99	117.22
C.V.	44.54	20.06	C.V.	47.14	25.86
Y-direction			*Y-direction*		
Mean	5.95	6.58	Mean	5.27	4.84
Min	2.01	3.14	Min	1.25	1.48
Max	14.76	13.14	Max	10.77	8.49
C.V.	5.26	4.34	C.V.	5.06	3.18
Z-direction			*Z-direction*		
Mean	8.83	26.32	Mean	35.22	30.47
Min	4.17	15.36	Min	22.19	16.73
Max	15.00	34.24	Max	46.31	38.10
C.V.	5.32	11.56	C.V.	14.87	10.58
	Right pelvic marker			***Left pelvic marker***	
X-direction	*Test I*	*Test II*	*X-direction*	*Test I*	*Test II*
Mean	129.29	91.67	Mean	125.94	89.32
Min	87.66	73.03	Min	77.45	67.65
Max	171.27	109.97	Max	172.90	110.51
C.V..	41.66	18.52	C.V.	47.82	22.58
Y-direction			*Y-direction*		
Mean	9.98	6.37	Mean	3.99	4.10
Min	6.10	1.40	Min	2.50	0.78
Max	18.28	12.18	Max	5.91	6.32
C.V.	5.21	5.17	C.V.	1.77	2.61
Z-direction			*Z-direction*		
Mean	34.33	25.04	Mean	32.09	27.59
Min	23.22	10.29	Min	20.11	7.52
Max	42.83	36.49	Max	42.04	37.70
C.V.	9.40	14.87	C.V.	11.75	14.86

In these studies, test-to-test reliability indicated reasonably constant repeatability. The lowest difference in C.V. values (4.2 % on both days) was obtained for the right knee landmark in the y-direction (Figure 3.2). The largest difference in C.V. values was for the left heel marker in the x-direction, with 108.5 % on day I and 47.0 % on day II. The results for the test-to-test reliability assessments for all markers are summarised in Table 3.5.

Linear velocity of landmarks

Linear velocity describes the rate of change of the translational motion (Bartlett, 1997a). As the results for the linear displacement assessments indicated that the strongest reliability was in the y-direction (vertical), only the findings of the landmark linear velocity in the y-direction are considered here. The lowest variability in linear velocity (10.7 %) was seen for the left pelvic marker. The largest variability was for the left heel marker, at 62.9 % on day I. The lowest differences in C.V. values were obtained for the left ankle landmark (38.63 on day I and 38.50 on day II) in the y-component. The largest difference in C.V. values was for the right hip marker with 17.76 on day I and 28.84 on day II. The results of these studies are presented in the Table 3.6.

Angular displacement of segments

Angular displacement describes the rotational component of the motion of the body segment moving in space. The angular displacement is represented in the global reference frame, which accounts for its description as the segmental angular displacement defining the absolute angular motion of the segment with respect to the horizon (section 2.5.2.3).

In order to further investigate gait performance reliability, segmental angular displacement was calculated for the foot, shank, thigh and pelvic segments for both legs. The findings of the saggital plane measurements are presented here.

Linear velocity of markers - saggital plane

	Right leg		*Left leg*	
	Day I (C.V.)	*Day II (C.V.)*	*Day I (C.V.)*	*Day II (C.V.)*
Ankle	33.39	41.66	38.63	38.50
Toe	40.07	38.07	47.63	39.92
Heel	40.52	44.90	62.92	60.86
Knee	15.97	12.55	27.29	25.72
Hip	17.76	28.84	26.94	30.67
Pelvis	19.40	26.50	10.72	15.44

Table 3.6 Within-test reliability: linear velocity. C.V. values were calculated from each marker's linear velocity in the y-direction on both testing days as described in Methods.

The lowest variability (2 %) in the segmental angular displacement was for the right pelvis. The values calculated for the right shank and thigh, and the left shank, thigh and pelvic segments were all < 5 %, again indicating low variability. The largest variability (11.4 %) was obtained during day I for the left heel marker. The results of these calculations are summarized in Table 3.7.

Table 3.7 Within-test reliability: angular displacement during the gait cycle. C.V. (%) values were calculated from each segment's angular displacement in the saggital plane during test I and test II as described in Methods (section 2.5.4).

Angular displacement of segments - saggital plane

	Right leg		*Left leg*	
Segment	*Day I (C.V.)* %	*Day II (C.V.)* %	*Day I (C.V.)* %	*Day II (C.V.)* %
Foot	11.37	6.18	12.16	9.70
Shank	4.09	2.27	5.66	4.95
Thigh	2.64	2.26	4.81	2.60
Pelvis	1.99	2.19	2.18	2.31

Angular velocity of segments

Angular velocity describes the rate of change of the rotational motions. In the present studies, segmental angular velocity was calculated for the foot, shank, thigh and pelvic segments on both affected (right) and unaffected (left) sides. The lowest variability values in the segmental angular velocity were 6.11% and 7.34% for the right pelvis on days I and II, respectively. The right shank and thigh and left shank, thigh, and pelvic segments provided variability of below 30%. The largest variability value (66.6%) was obtained during day I for the left shank marker. The results of these investigations are shown in the Table 3.8.

Table 3.8 Within-test reliability: segmental angular velocity during the gait cycle. C.V. (%) values were calculated from each segment's angular velocity in the saggital plane during test I and test II as described in Methods.

Angular velocity of segments - saggital plane				
	Right leg		*Left leg*	
Segment	*Day I (C.V.)*	*Day II (C.V.)*	*Day I (C.V.)*	*Day II (C.V.)*
	%	%	%	%
Foot	49.17	59.25	44.83	41.63
Shank	24.10	24.41	66.60	41.13
Thigh	17.23	19.21	37.66	26.78
Pelvis	6.11	7.34	29.21	48.30

Joint angular displacement

During angular displacement of a joint, the vector is represented in the body-fixed reference frame of the adjacent body segment (e.g. the distal segment), because it describes the relative angular motion of the segment with respect to another (Methods section 2.5.2.3). In order to further examine the reliability of gait variable measurements, the angular displacement was calculated for the ankle, knee, and hip joints on both legs. The lowest variabilities in angular displacement were values of 2.24 % and 2.34 % obtained for the right hip on days I and II, respectively. The right knee and left hip yielded values of 5 % on both days; a similar value was obtained for the *right ankle* on day II. The largest variability (9.2 %) was recorded on day I for the left knee. The results of these calculations are shown in Table 3.9.

Table 3.9 Within-test reliability: angular displacement of joints during the gait cycle. C.V. (%) values were calculated from each joint's angular displacement in the saggital plane during test I and test II as described in Methods.

Joints' angular displacement - saggital plane				
	Right leg		*Left leg*	
Joint	*Day I (C.V.)*	*Day II (C.V.)*	*Day I (C.V.)*	*Day II (C.V.)*
	%	%	%	%
Ankle	7.23	4.88	9.20	5.97
Knee	2.71	3.06	4.74	2.61
Hip	2.24	2.34	6.19	6.30

Joint angular velocity

As indicated earlier, joint angular velocity describes the rate of change of the rotational motions using the body-fixed reference frame of the adjacent body segment (section 2.5.2.3). The results described below were obtained from joint angular velocity calculations of subjects' ankle, knee, and hip for both legs. The lowest variability value determined for joint angular velocity was 19.43 % for the right hip on day I, which increased to 40.79 on day II. The largest variability occurred with the right ankle joint, at 95.22 % and 99.35 % on day I and II, respectively. The results of these calculations are presented in the Table 3.10.

Table 3.10 Within-test reliability: angular velocity of joints during the gait cycle. C.V. (%) values were calculated from each joint's angular velocity in the saggital plane plane during test I and test II as described in Methods.

Joints' angular velocity - saggital plane				
	Right leg		*Left leg*	
Joint	*Day I (C.V.)* %	*Day II (C.V.)* %	*Day I (C.V.)* %	*Day II (C.V.)* %
Ankle	95.22	99.35	90.28	79.41
Knee	27.51	37.88	91.21	82.52
Hip	19.43	40.79	41.41	67.03

3.1.2 Discussion

3.1.2.1 Balance test reliability

The reliability of balance measurement data collected using force platform apparatus was monitored regularly to ensure applicability in a clinical setting. Details of the CoP co-ordinates and shear forces in a-p and lateral directions recorded for healthy subjects' were obtained to assess the control of static standing. For each of the variables measured, comparisons were made between the results obtained on the same day, and between several tests undertaken over the 14 weeks testing period. Whilst both of these comparisons were relevant for the main study, as a main aim of the research was to assess the effects of DAFOs over three months, from a clinical perspective, the latter were most appropriate.

The results of the first of these assessments (section 3.1.1.1) showed that the within-test reliability C.V. values of the balance parameters remained steady and mainly under 5%, indicating good reliability for variables obtained during recording sessions carried

out on the same day. The shear force parameters determinations (Fmean, Fsd and Fslope) provided slightly lower average C.V. values than for CoP, again signifying good within-test reliability. Goldie *et.al.* (1996) tested the balance reliability with healthy subjects and compared the CoP and forces. These authors found that reliability between tests, which was repeated on the same day, was better for forces than CoP measures.

Collectively, the between-test reliability C.V. value determinations for the shear force variables and CoP were always < 10 % and 20 %, respectively. As these comparisons reflect reliability data collected over the entire testing period (14 weeks) such levels are reasonable, and are comparable to findings obtained using similar methods and healthy subjects reported elsewhere (Burnfield *et al.*, 2000; Gefen, 2001).

The C.V. of the CoP values determined for lateral sway (reflecting the hip movements) tended to be lower than for a-p (reflecting the ankle motions) in all tests. Lateral sway is a reliable measure because adjustments for postural sway in the lateral direction are smaller at the hip, which is located relatively close to the body's centre of gravity (Maki *et al.*, 1992). The reliability of the shear force measures was shown to be good both within- and between-tests (in all cases < 5 %) indicating that, overall, the subjects used a relatively consistent pattern of postural control during static standing. Similar results have been reported from earlier investigations, where measures derived from postural forces or displacement of CoP were compared (Burnfield *et al.*, 2000). The present finding that C.V. values of shear force measurements were generally higher in the lateral direction than in the a-p direction is interesting. It has been speculated that age-related changes may affect lateral stability of shear forces, which stabilizes responses occurring at the hip, and this lateral instability may be an intrinsic factor contributing to balance problems (falls) in the older population (McClenaghan *et al.*, 1995). Here, the healthy subjects were of a similar age to the stroke subjects in the main study and can therefore be described as elderly people. The results obtained are consistent with the

reliability of postural control in the lateral direction being reduced as a consequence of aging, but nevertheless achieving good levels of experimental reliability. The sd and slope variables of shear forces provided the lowest C.V. values, indicating the strongest reliability for these within-test variables. The results indicate that shear forces are somewhat more sensitive to re-test reliability assessment in detecting changes of postural steadiness than CoP measures, although both measures provided acceptable levels, both within- and between-tests.

The literature contains few accounts of reliability studies applicable to the work reported here. Goldie *et al.* (2000) reviewed the validity of balance measurements for healthy subjects and highlighted a lack of consensus concerning basic validity, and the availability of limited evidence supporting the validity of any given measurement. However, more recently, Ghent *et al.* (1992), Dickstein *et al.* (1993) and Liu and Lawson (1995) reported findings of studies on healthy subjects using balance measurements similar to those undertaken here, which indicated good reliability for non-disabled subjects. Dickstein *et al.* (1993) also presented moderate balance reliability data for a subject with hemiplegia. In a larger study, Levine *et al.* (1996) examined the reliability of force platform apparatus using 20 stroke subjects; the main finding of this work showed that, in static balance tests, measurements in the medio-lateral direction provide better reliability than in the antero-posterior direction.

It is noted here that whilst the reliability studies carried out within the present work were important, force platforms are subject to many inherent characteristics and influences, which can perturb the reliability of the data obtained. For example, the accuracy of the force platform data output can be affected by electronic noise, system hysteresis and drift, non-linearity and different offset voltages of the transducers. However, for the present work, it was taken that as the force platform had been installed and maintained in accordance with the manufacturer's requirements, it was functioning within the quoted specification. A check was however made on system drift and it was confirmed

to be negligible for the 30 s testing periods employed in this work (Dr. J. Richards, personal communication). The existence of inconsistencies in procedures used for establishing the reliability of force platform apparatus both within- and between-gait laboratories has been commented upon elsewhere (Browne and O'Hare, 2000). These authors have proposed comprehensive quality control procedures for force platforms in detail. This issue is addressed in the Future Studies section of this thesis.

Accuracy of gait performance

The studies performed to clarify which method for digitising the markers (manual tracking or semi-automatic) was most accurate for assigning 3-D co-ordinates to the positions of the lower limb joints in the video picture images, and to measure stability levels of calculated variables (section 2.5.3) were undertaken to investigate digitising accuracy and the propagation of variation from the digitised co-ordinate level throughout the whole analysis sequence. In addition, these studies enabled assessment of variation in gait performance at the 3-D co-ordinate level and isolation of inaccuracies due to the operator.

Effects of repeated digitising on co-ordinates

Analysis of linear displacement data in a single gait cycle of a stroke subject were done from 16 repeated digitisation. Calculations were processed separately for 12 body landmarks and for each co-ordinate of the segmental model (in x, y and z-directions) via the manual method (section 3.1.1.2), which provided clearly lower values for the left side (for 14 landmarks) compared to the semi-automatic method. A similar (albeit less noticeable) situation was apparent for the right side. Interestingly, the semi-automatic method yielded lower RMSE percentage for the right knee joint compared to the manual method in all 3-D co-ordinates. This may have been due to the fact that the subject wore shorts and this joint was visible within the body landmark throughout the gait cycle. In addition, whilst every effort was made to position the cameras accurately, the

possibility that slight differences in camera angle on the right side resulted in improved automatic marker calculation and accuracy cannot be excluded. (Bartlett, 1997a; Salo *et al.*, 1996).

The manually digitised landmarks provided better accuracy for the ankle and knee joints on the left side for all of the 3-D co-ordinates selected. Furthermore, using this method, the foot, heel, hip and pelvis on the left side, and the foot on the right side, yielded lower RMSE percentages in some (2) directions, a situation not seen when using the semi-automatic technique. This could have been due to the bright light near the marker leading to reproducibility errors with the semi-automatic technique, which was eliminated ('visually') by the operator using the manual method.

Effects of repeated digitising on variables

The RMSE values for the 8 manually repeated digitisations were used to provide a measure of the stability provided by the 3-D co-ordinates. For these assessments (section 3.1.1.2), high root mean square error (RMSE) values were consistent with poor repeatability and the potential for difficulties when reproducing the same motion; conversely, lower RMSE values are considered indicative of good levels of stability (Allard *et al.*, 1996). RMSE values in x, y and z directions showed that the y-axis exhibited the greatest stability for repeated measurements for each body landmark. Manual digitising provided RMSE values of < 5% for each body landmark in the y-direction; the average values for all joints/markers were 2.7 and 1.7 % for displacement and velocity, respectively. The largest variation was evident when the landmark was obstructed from a camera view by another part of the body. Thus, for this subject group, occasionally the view of the video picture was obscured partially because, for personal reasons, some elderly patients opted to wear light, but loose fitting (baggy) shorts or shirts. In addition, where subjects possessed a severe gait disability, there were occasions where an affected arm masked trunk and hip movement. It proved possible to

eliminate some of the inaccuracy and variation during data collection via smoothing (Lundberg, 1996; Maynard *et al.*, 2003; Salo *et al.*, 2003).

Overall, the foot and heel landmarks and ankle joint results were steadier (lower RMSE values) than those obtained for the knee, hip and pelvis. Nonetheless, the variability of the knee, hip and pelvic values was at acceptable levels of accuracy for 3-D co-ordinates, with over 60 % of all variable estimates providing RMSE values of < 5 %. Such accuracy levels during digitising probably reflect the efficient set-up procedure used in relation to the number and location of the cameras in the gait laboratory (Borghese and Ferrigno, 1990; Klein and DeHaven, 1995). The y-direction provided the lowest variability for all landmarks in both raw- and smoothed-data calculations, which is also explained by effective camera positioning and the clear on-screen views of these joint centres. During manual digitisation, a potential problem is the introduction of error by the operator when selecting the centres of joints or reflective markers. Olney *et.al.* (1994) estimated that the magnitude of such error to be 1 RMSE from different values for a repeated digitised data point.

There are no earlier reports of movement analysis and reliability studies comparable to those undertaken for the present research using stroke patients. Earlier work has focused on examining the variability and reliability of different opto-electric systems in relation to normal human performance and the behaviour of mechanical objects, or in a sports science setting. However, some useful comparisons can be made with such studies. Vander Linder *et al.* (1995) examined a healthy subject when walking using 'stand-up' tests with a direct processing method, which involved microchip controlled monitoring of a wooden bar. Results were given as the mean difference of repeated measurements within-trial and yielded values of between 1.39 and 3.04 mm. Salo and Grimshaw (1987) monitored reliability measurements of hurdle runners on an athletic track using a video-based system similar to that used here. Differences between

independent digitising indicated that although the reliability of the majority of parameters remained under 1 cm, in some cases, there was substantial error.

The present studies showed that whereas manual digitising is a relatively slow method for processing gait data compared to the semi-automated method, it enables the collection of more stable and reliable results, which facilitates the generation of more useful information in relation to the applied biomechanics of gait performance with stroke walkers.

Reliability of gait measurements

The reliability of gait performance for a stroke subject was also examined using multiple gait tests on the same day (four separate gait tests), and between multiple trials carried out on different days (one week between testing days, section 2.6.4). The following discusses the most important findings in relation to specific landmark, segment and joint parameters of the gait cycle.

Linear displacement and velocity of landmarks

The clearest findings of the study of test-to-test reliability achieved on the same day were the low variability for different landmarks during stance phase and the greater variability during swing phase. This was predictable, as during stance phase the joints' motions are limited by contact with the ground, whereas there is a greater potential for joint movement during swing phase (Romkes and Brunner, 2002). The ankle, knee and hip joints provided the lowest linear displacement estimates in the y-direction, with 80 to 95 % of the values yielding < 10 mm variation in a full gait cycle. These findings are in good agreement with earlier reports of movement analysis studies with video-based kinematic gait tests (Kadaba *et al.*, 1990; Growney *et al.*, 1997; Romkes and Brunner, 2002). It was also found that variability of landmarks in the y direction (vertical) was considerably lower than in the x- and z-directions, indicating that the data for the joint motions in the vertical direction had better reliability with this technique. This finding is

compatible with gait performance reliability studies reported by Murray (1967) and Winter (1974) who showed that, in healthy subjects, the maximum magnitude of motions (ankle, knee and hip) in the vertical direction was consistent in within- and between-subject assessments. In agreement with the present studies, several earlier reports have described how estimates of the other components of movements (x-direction and z-direction) at the lower limb joints are less consistent than obtained in the y-direction. Apkarian *et.al.* (1989) described inter-subject variations in both gait pattern and maximum magnitude for healthy subjects. These authors postulated that the error was caused, at least in part, by inter-individual repeatable artefacts, such as skin movement and/or limited system resolution (Salo *et al.*, 1997; Bartlett, 1997a). In addition, difficulties in obtaining high repeatability may be caused by inappropriate marker placement assessment. This is a contentious issue and is subject to debate. Poorer reproducibility of kinematic variables may be due to problems in accurate placement of markers on the surface anatomical landmarks (Maynard *et al.*, 2003).

In the present work, it was found that the maximum difference between the C.V. values in the x-direction of two separate testing days was 108.5 in test I and 47.0 in test II, reflecting more than 23 cm variation for the right (affected leg) heel landmark. It is possible that the high variability of heel landmark movements in the x-axis between tests is associated with the variation of the stroke subjects' gait pattern, when the shank muscles (tibialis anterior muscle) are weak. The between-day reliability was good, overall, particularly in the y-direction, where the majority of the landmarks (12) yielded C.V. values of under 6 %; 3 provided values of under 3 %. These values compare favourably with biological systems in general, where, by convention, C.V. values of 10-15 % are considered acceptable as clinical measures (Olney *et al.*, 1979; Winter, 1984; Stokes, 1986; Evans *et al.*, 1997). This arbitrary C.V. range is adopted for most published studies involving patients, irrespective of study sample size.

The data obtained for linear velocity for all body landmarks obtained on day I and day II indicated markedly higher C.V. values than for linear displacement (Table 3.6). Again, the heel marker provided the lowest overall reliability values; the highest between-day variability was obtained for the pelvic marker, perhaps reflecting steadier movements of the hips than for heel function during the gait cycle. These observations are also in accord with earlier published findings (Growney *et al.*, 1997; Romkes and Brunner, 2002). Collectively, this work shows that the strongest reliability is provided in the y-direction, both within one-day tests and between the two-day tests, which, in the context of the present research aims, provided an acceptable level of gait performance variation for the study of disabled walkers. As the primary movement of normal gait occurs mainly in the saggital plane, subsequent discussion in this thesis is limited to flexion-extension motion of the lower limb joints in this plane.

Angular displacements and velocities of segments and joints

In order to provide further details on the reliability of subjects' gait performance affected by stroke measurements obtained within- and between-test, further calculations were made of the variability of both segments' (global reference frame) and joints' (body fixed reference frame) angular displacement and velocity. The majority of the angular displacement of lower limb segments (shank, thigh and pelvic) data indicated good within-test variability levels (C.V. < 5 %) for day I and day II sessions (4 tests on each day), with only the foot segment (on both sides) yielding values of > 10 %. The test-to-test repeatability measures indicated repeatable gait performance with values of < 2 % from shank to pelvis on both legs. The findings of the angular velocity of segments calculations provided similar results as for the displacement assessments, with better reliability evident with the higher segments of the lower limbs both within- and between-day tests. A clear finding from these studies was that the velocity values were higher and less reliable than those for the displacements. This is partly explained by the

method of the velocity (mm/s) calculation (the first order derivative of the displacement data), which tends to multiply the error (Wu, 1995b).

Joint angular displacement and velocity determinations produced similar findings to the segmental measurements. The hip, and knee joints displacements provided C.V. values of < 7 %, whereas the ankle joints yielded the lowest values within one-day tests. However, the joint velocity values changed dramatically and showed clearly increased values, particularly between-day tests. For example the right (affected) hip was 20 % in day I and 41% in day II. The right ankle variability was poorest with 99.4 % and 95.2 %, in the day I and II tests respectively.

Collectively, these comparisons of alternative methods used to calculate gait movements show that segmental values yield slightly better reliability estimates for both displacement and velocity measures both within- and between-testing days. Comparable findings, in earlier studies where similar methods were used, have been reported, e.g. Morris (1973), Gilbert *et al.* (1999) and Maynard *et al.* (2003). In addition, the present work demonstrated that the motions for both measurement systems exhibit increased variability for the ankle joint and foot segment. Radin *et al.* (1991) and Wu (1995a) reported similar findings from studies of healthy subjects, where larger angular velocity of the more distal joints led to differential gait velocities, which was speculated to introduce error in joint movement data.

The biomechanical literature contains many reports of studies on test variability and reliability of dynamic movements. Samuelson *et al.* (1988), Scholz and Millford (1998), Hanke (1991) and Haggard and Wing (1996) reported mostly high reliability values. Although all these studies were carried out using automatic systems and did not involve human movements, it is generally agreed that they have some, albeit limited use for clinical research. Motion analysis studies of walking and running tests that investigate variability or repeatability, which are closely related to reliability, have been carried out by Kadaba *et al.* (1990), Growney *et al.* (1997) and Winter (2002). In a recent study,

Maynard and colleagues (2003) evaluated intra-rater reliability with 10 healthy subjects (measured in same day) and inter-rater reliability with 19 healthy subjects (measured by three examiners) from repeated gait measurements. One gait cycle was analysed and ankle, knee and hip joint kinematic evaluated in the saggital plane. Overall, the study indicated good reliability, although the authors speculated that gait kinematic parameters are more difficult to reproduce than kinetic parameters. The best test-retest reliability was found to be the knee angle; the poorest reliability was for the hip angle. It was also suggested that data collected from a single gait cycle might be easier to interpret clinically if supported by information gained via other methods of analysis (Maynard *et al.*, 2003).

The present studies provide novel evidence for tests involving a stroke patient, where reasonable levels of gait kinematic error within- and between-days tests can be achieved via video-based movement analysis, and that such kinematic (segment) parameters in the saggital plane can be studied effectively by these methods. It is emphasised here that whilst, overall, the data presented are consistent with acceptable levels of reliability for clinical purposes, they were obtained via assessment of a single subject. As the disability levels of stroke patients are inherently heterogeneous, it cannot be assumed that the findings described here are applicable to a larger population. Such heterogeneity, which may be present both within- and between-subjects, also applies to the pathological events (in this case balance disturbance) which manifests as a disability. Nonetheless, whilst accepting this unavoidable limitation, these findings provided an indication of method reliability applicable to this study and afforded a reference point for further investigations. The following sections present the results of the work on the stroke subject groups (control and experimental) balance and gait (foot, shank and thigh segment rotation in the saggital plane) during the main phase studies.

3.2 Main phase - Balance

This section presents the results of balance tests performed during the main study phase of the research. These investigations used protocols that were modified in accordance with the findings of the preliminary work presented earlier and in Appendix I. During the balance tests, to gain comprehensive information, the effects of the orthosis were evaluated via measurement of several standing balance variables. Data comparisons were made between the control group (shoes users) and the experimental group (DAFO users). The experimental group subjects were also assessed under two different conditions: using either the DAFO or shoes-only. The rationale for studying the subjects with and without the device was that this approach could identify the direct effects of the DAFO separate from unrelated influences such as learning and recovery effects. The *p* value for all statistical comparisons was 0.05.

The results reported here are divided into three subsections. In the first section, comparisons of the demographic characteristics of the subjects studied are presented. The second section describes the velocity of sway of standing balance in relation to subjects' age, sex and gender. In the third section, the effects of DAFOs on subjects' CoP sway index and F(mean), F(sd) and F(slope) of horizontal forces in a-p and lateral directions are given.

3.2.1 Results

3.2.1.1 Subject characteristics

Stroke subjects

195 subjects were considered for inclusion in the study. Of these, 22 subjects were recruited successfully and 18 completed the main phase of the balance studies (8 control, 10 experimental). The reasons for failure to complete the trial were further health problems (2), moving residence (1) and other personal reasons (1). The

demographic characteristics and distribution details for the subjects who completed the trial are shown in Table 3.11.

Table 3.11 Demographic details of subjects who completed the balance tests

Group	Sex	Age in years	Side of paresis	TS in months	Weight in kg	Height in cm	Walking aids
CNTRL							
	4 F 4 M	66.3 (52-76)	7 left 1 right	7.5 (4-15)	71.5 (50.9-92.4)	163.2 (153-173)	No aids (6) Stick (2)
EXP							
	3 F 7 M	68.9 (54-87)	5 left 5 right	8.2 (4-15)	74.3 (61.2-92.4)	166.6 (153-174)	No aids (2) Stick (7) Frame (1)

Mean and (range), TS = time since stroke

Within the control and experimental groups, values for subjects' age, weight and height were found to follow a normal distribution ($p > 0.01$, Dallal and Wilkinson approximation to Lilliefors' method). It was determined that the mean values for each factor were not significantly different between groups ($p < 0.05$, unpaired *t*-test). However, the differences in the walking aids used by the subjects (Table 3.11) might suggest some variation in mobility levels between the groups.

Healthy subjects

Healthy elderly subjects ($n = 4$) were recruited in order to construct a comparative database for each variable. The repeated measurements for this were obtained during a single testing day undertaken for each subject. The demographic characteristics of the healthy subjects tested are shown in Table 3.12.

Table 3.12 Demographic details of the healthy elderly subjects

Subject	Sex	Age in years	Weight in kg	Height in cm
HE1	M	69	88.4	167
HE2	M	72	73.5	175
HE3	F	72	67.0	158
HE4	F	73	64.0	152
Mean		71.5	73.2	163
Range		69 - 73	64 - 88	152 - 175

Subjects' age, height and weight were comparable with the stroke patients of the control and experimental groups, as presented earlier, $p < 0.05$, unpaired *t*-test.

3.2.1.2 Functional ability in everyday life

Stroke subjects' functional abilities were assessed for each of the three tests during the twelve weeks study period using ADL assessment scales by interview. For all subjects, the Nottingham Extended ADL and Rivermead assessment scales were used. These scales were employed to evaluate subjects' changes in post-stroke impairment and disability, and their ability to carry out more difficult, daily functional tasks, such as using public transport, housework, social activities and hobbies (section 2.3.).

In the control group, the mean score from the three tests for the Nottingham Extended ADL scale was 39 (18-61), mean and (range). Using this scale, the experimental group scored 31 (11-43). These values suggest a difference in scores between the control and experimental groups, but this did not achieve statistical significance ($p = 0.315$, Mann-Whitney U-test). The Rivermead Motor Assessment scale consists of two parts: the Functional scale and the Leg and Trunk scale. In the control group a functional score of 10 (7-11) was recorded for the three tests; in the experimental group the score was 8

(3-11). These score values were not significantly different (p = 1.457, Mann-Whitney U-test). Application of the leg and trunk scale provided scores of 5 (2-6) and 3 (1-5) for the control and experimental groups, respectively. The difference between these values was of borderline significance (p = 0.055). Examination of within-group data indicated minimal differences in scores from the baseline tests to the third tests for both the Nottingham ADL and Rivermead assessment scales. The results of these measurements are summarised in Table 3.13 (control group) and Table 3.14 (experimental group).

3.2.1.3 Velocity of sway

The velocity of sway is the sum of the amount of displacement of the CoP divided by the sampling time, and is used to describe the subjects' ability to overcome instability in the upright posture. A consensus is that lower values of velocity of sway reflect more adequate balance control (Winter, 1995; Nougier *et al.*, 1997).

Antero-posterior direction: eyes-open condition

In the baseline test, the control group' a-p velocity of sway with eyes-open was 20.49 mm/s (5.75), mean and (SD). The values recorded for the second and third tests remained at similar levels, 20.81 mm/s (6.95) and 19.30 mm/s (3.52), respectively. In the experimental group, for two different trials (using shoes alone and then DAFOs), the baseline velocities of sway were similar to the control group, at 20.16 mm/s (6.12) and 21.10 mm/s (7.3), respectively. In the second tests, the values recorded were 20.75 mm/s (8.39) with shoes and 20.25 mm/s (5.92) with DAFOs. For the third tests, the values were lower with shoes (mean 18.92 mm/s, SD 4.76), but not with DAFOs (mean 21.51 mm/s, SD 10.11). The comparative data from the healthy elderly subjects with eyes-open was 19.47 mm/s (3.50).

Table 3.13 Summary of activities of daily living tests in the control group (n = 8). Mean, standard deviation, and minimum/ maximum values for each test are shown. Summary statistics for the three tests are shown in the Mean column.

	Scale											
	Nottingham ADL scale (Max 63)				**Rivermead Motor Assessment: Functional Test** (Max 13)				**Rivermead Motor Assessment: Leg and Trunk Test** (Max 10)			
CNTR	Test I	Test II	Test III	Mean	Test I	Test II	Test III	Mean	Test I	Test II	Test III	Mean
C1	12	20	25	19	6	6	9	7	2	2	3	2
C2	14	16	23	18	10	9	10	10	6	3	5	5
C3	61	61	62	61	10	11	11	11	4	4	6	5
C4	53	57	55	56	11	11	10	11	8	4	7	6
C5	32	33	33	33	10	11	11	11	5	5	5	5
C6	20	28	24	24	6	8	7	7	3	2	4	3
C7	58	50	50	53	11	11	10	11	7	7	4	6
C8	51	52	54	52	10	11	11	10	5	5	5	5
Mean	**38**	**40**	**41**	**40**	**9**	**10**	**10**	**10**	**5**	**4**	**5**	**5**
SD	**20**	**17**	**16**	**18**	**2**	**2**	**1**	**2**	**2**	**2**	**1**	**1**
Min	**12**	**16**	**23**	**18**	**6**	**6**	**7**	**7**	**2**	**2**	**3**	**2**
Max	**61**	**61**	**62**	**61**	**11**	**11**	**11**	**11**	**8**	**7**	**7**	**7**

Table 3.14 Summary of activities of daily living tests in the experimental group (n = 10). Mean, standard deviation, minimum/ maximum values for each test are shown. Summary statistics for the three tests is shown in the Mean column.

	Scale											
	Nottingham ADL scale (Max 63)				**Rivermead Motor Assessment: Functional Test** (Max 13)				**Rivermead Motor Assessment: Leg and Trunk Test** (Max 10)			
EXP	Test I	Test II	Test III	Mean	Test I	Test II	Test III	Mean	Test I	Test II	Test III	Mean
E1	27	22	28	26	8	8	8	8	1	1	2	1
E2	16	23	13	17	5	5	5	5	3	4	2	3
E3	41	40	40	40	10	10	11	10	3	3	4	3
E4	45	43	40	43	11	11	11	11	5	5	5	5
E5	36	43	46	42	6	8	8	7	5	4	4	4
E6	41	42	42	42	8	10	10	10	3	4	4	4
E7	33	28	25	29	9	9	10	9	3	3	3	3
E8	23	24	31	26	6	8	11	8	4	4	4	4
E9	12	9	11	11	5	1	3	3	3	1	2	2
E10	24	35	38	32	9	10	10	10	3	3	4	3
Mean	**30**	**31**	**31**	**31**	**8**	**8**	**9**	**8**	**3**	**3**	**3**	**3**
SD	**11**	**12**	**12**	**11**	**2**	**3**	**3**	**3**	**1**	**1**	**1**	**1**
Min	**12**	**9**	**11**	**11**	**5**	**1**	**3**	**3**	**1**	**1**	**2**	**1**
Max	**45**	**43**	**46**	**43**	**11**	**11**	**11**	**11**	**5**	**5**	**5**	**5**

Antero-posterior direction: eyes-closed condition

Under this condition, the a-p velocities of sway values recorded were, overall, higher than in the eyes-open condition. Thus, in the control group, with eyes-closed, the mean a-p velocity of sway for the baseline test was 23.59 mm/s (12.28); similar data were recorded for the second (22.75 mm/s SD 8.75) and third (23.15 SD 8.76) tests. A similar level was recorded for the healthy elderly subjects, although the SD values indicated noticeable less variation for these subjects (mean 23.00 mm/s and SD 3.78).

In the experimental group, a-p velocity was consistently higher compared to the control group in all three tests. Thus, for the baseline test the values recorded were 26.13 mm/s (11.1) with shoes and 25.26 mm/s (8.55) using DAFOs. In the second test, the velocities were 25.02 mm/s (10.38) with shoes and 25.61 mm/s (8.81) with DAFOs, and in the third test, 24.60 mm/s (9.05) and 24.81 mm/s (10.07), with shoes and DAFOs, respectively. When these CoP velocity values were examined within the experimental group, the results indicated no differences between shoes and DAFOs over the three tests (Figure 3.4). Statistical comparisons of velocity data were performed as before; no significant differences were evident over the testing period. The results (*f* and *p* values) for these analyses are summarised in Table 3.15 a.

When the data for the experimental group were separated according to side of paresis, it was found that for the 5 subjects with left side paresis, the a-p velocity of sway with eyes-open was 18.66 mm/s (5.14) with shoes and 19.46 mm/s (4.77) with DAFOs. For the 5 subjects with right side paresis, a-p velocity increased to 21.22 mm/s (7.16) with shoes and to 22.45 mm/s (9.69) with DAFOs. In the eyes-closed condition, the mean a-p velocity of sway of the subjects with left side paresis was calculated at 22.29 mm/s (6.74) using shoes and 22.07 mm/s (4.87) using DAFOs; for the right side paresis subjects the values were 28.20 mm/s (11.79) with shoes and 28.37 mm/s (10.90) with DAFOs.

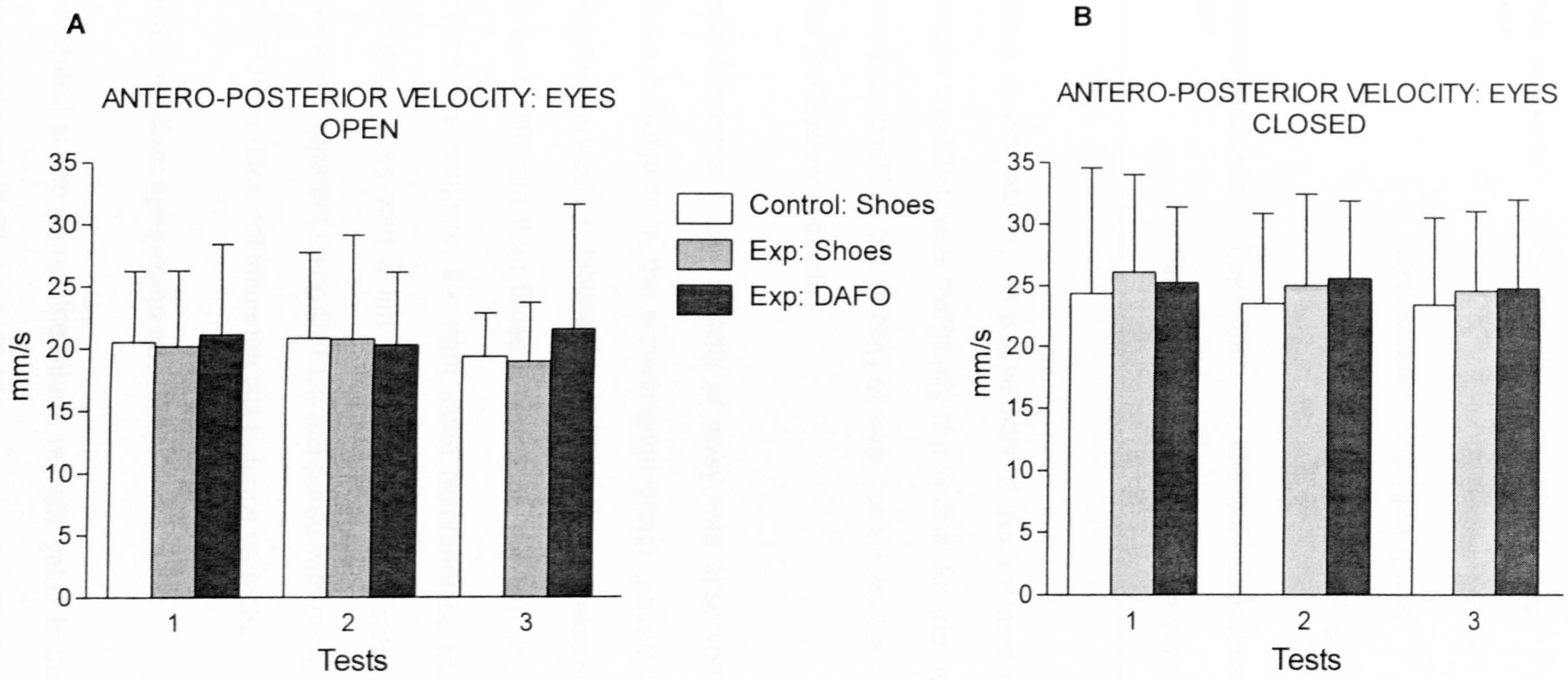


Figure 3.4 Antero-posterior velocity values recorded during 30 s balance tests with subjects' eyes open (A) and eyes closed (B). Control subjects (n = 8) were tested wearing their own shoes. Experimental subjects (n = 10) were tested separately with their shoes and when wearing DAFOs. Measurements for all subjects were recorded in the 3 testing sessions as described in Methods. Data are mean and SD.

Table 3.15 a Statistical tests (ANOVA) of the velocity of sway in the a-p direction

	Condition	Source comparison	*f*	*p*
Within subjects factor	Eyes-open	1) Time*group	3.37	0.08
		2) Device*group	1.82	0.19
	Eyes-closed	1) Time*group	0.02	0.88
		2) Device*group	1.30	0.27
Between subjects factor	Eyes-open	Control - Experimental	0.77	0.39
	Eyes-closed	Control - Experimental	0.05	0.81

For these investigations, the a-p velocity of sway values for the stroke subjects in the eyes-open condition were marginally higher than for the healthy elderly subjects. In the eyes-closed condition, the velocity of sway for the stroke subjects was noticeably higher than for the healthy subjects.

A clear difference in a-p velocity of sway was observed between left and right side hemiparesis subjects in the experimental group (paired *t*-test, $p < 0.05$). Right-sided hemiparesis subjects exhibited consistently higher velocity of sway, but not statistically significance different than those affected on the left side. The higher values suggest that, for these subjects, the right sided hemiparetics possessed poorer a-p balance control than those with a left side deficit. No statistically significant changes in a-p velocity were apparent using DAFOs compared with using shoes alone, which suggests that DAFO use does not influence this balance variable.

Lateral direction: eyes-open condition

In the control stroke group, the lateral velocity value in the eyes-open condition for the baseline test was 25.07 mm/s (7.11), mean and (SD). Similar values were recorded for

the second (mean 24.41 mm/s, SD 6.68) and third (mean 25.41 mm/s, SD 7.43) tests. In the experimental stroke group, using shoes alone and then using DAFOs, the lateral velocity values for the baseline test were 22.09 mm/s (4.86) and 23.26 mm/s (6.77), respectively. Corresponding values for the second (mean 22.26 mm/s, SD 4.90; mean 22.99 mm/s, SD 5.94) and third (mean 21.51 mm/s, SD 7.43; mean 21.40 mm/s, SD 4.13) tests were very similar. The comparative database from the healthy subjects provided very similar lateral velocity of sway values as for the control group (mean 25.58 mm/s, SD 6.44).

Lateral direction: eyes-closed condition

In the control group, the baseline value recorded for lateral sway was 26.76 mm/s (8.17); slightly lower values were obtained for the second (mean 25.81 mm/s, SD 7.81) and third (mean 25.49 mm/s, SD 5.05) tests. In the experimental group, lateral velocity for the baseline test was 22.93 mm/s (4.91) mm/s using shoes and 24.17 mm/s (8.17) using DAFOs. Minimal differences were evident in the second test (22.81 mm/s (SD 4.86) with shoes and 23.26 mm/s (SD 6.77) with DAFO) and third tests (22.72 mm/s (SD 4.05) with shoes and 23.75 mm/s (SD 4.92) with DAFO). The lateral velocity of sway in the healthy elderly subjects with eyes-closed was 29.49 mm/s (10.49), mean and (SD).

Overall, the experimental group data clearly revealed lower lateral velocity of sway values than for the control group throughout all three tests under the eyes-open (and eyes-closed) conditions. The mean and SD for the lateral velocity values recorded for control and experimental groups in the each of the tests and under the two experimental conditions are summarized in Figure 3.5. Statistical comparisons for the lateral sway data were carried out (ANOVA) and these indicated no statistically significant differences within- and between-groups over the testing period. The *f* and *p* values for these analyses are summarised in Table 3.15 b.

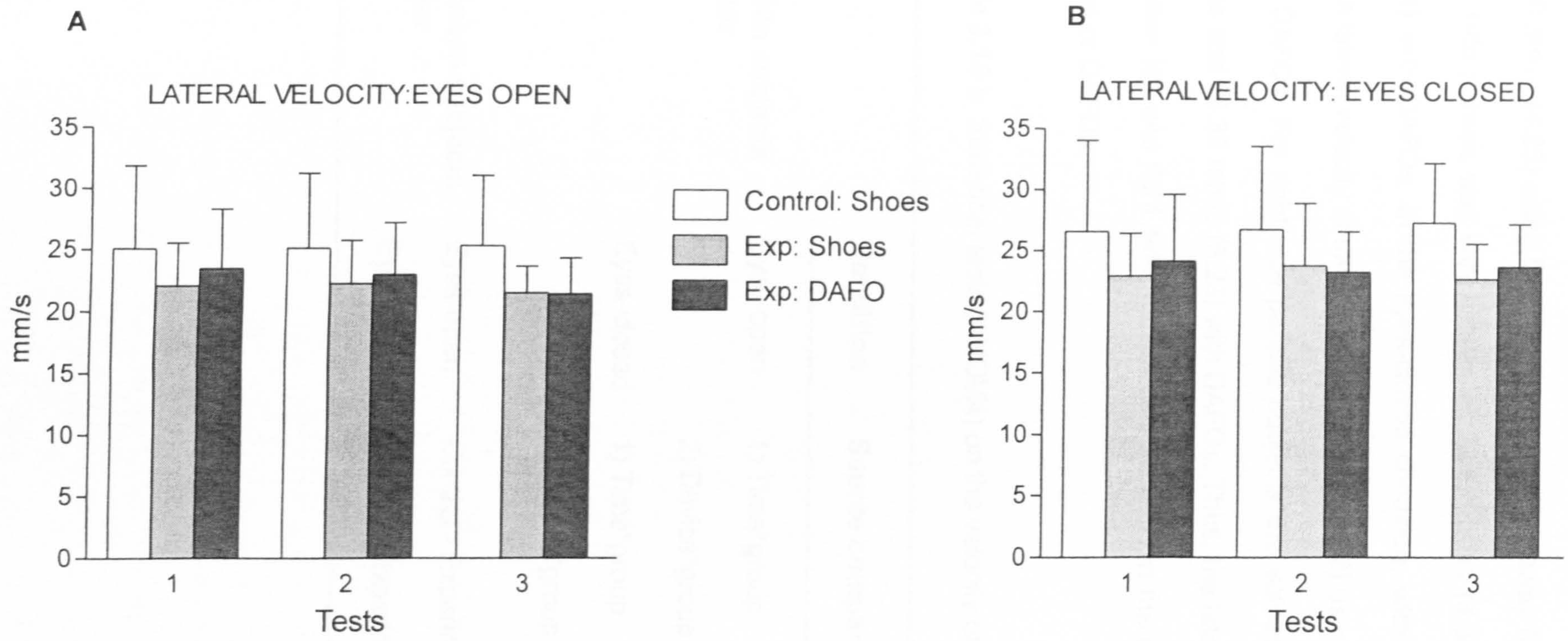


Figure 3.5 Lateral velocity values recorded during 30 s balance tests with subjects' eyes open (A) and eyes closed (B). Control subjects (n = 8) were tested wearing their own shoes. Experimental subjects (n = 10) were tested separately with their shoes and when wearing DAFOs. Measurements for all subjects were recorded in the 3 testing sessions as described in Methods. Data are mean and SD.

Further statistical analyses were performed using the experimental group data separated according to side of paresis. The 5 subjects with left side paresis had a mean lateral velocity of sway in the eyes-open condition of 21.32 mm/s (3.84) using shoes and 22.60 mm/s (4.25) using DAFOs. The velocity of sway for the other 5 subjects who had right side paresis was very similar, at 22.57 mm/s (4.34) with shoes and 22.63 mm/s (5.74) with DAFOs. In the eyes-closed condition, with left side paresis subjects, the mean lateral velocity of sway was 22.0 mm/s (4.02) using shoes and 23.05 mm/s (4.30) with DAFOs. For right side paresis subjects the values were 24.32 mm/s (6.32) with shoes and 24.39 mm/s (6.23) with DAFOs. Thus, the lateral velocity of sway was similar between left and right side hemiparesis subjects in the experimental group when using shoes or DAFOs.

Table 3.15 b Statistical tests (ANOVA) on the velocity of sway in the lateral direction

	Condition	Source comparison	*f*	*p*
Within subjects factor	Eyes-open	1) Time*group	0.49	0.49
		2) Device*group	0.33	0.57
	Eyes-closed	1) Time*group	0.001	0.97
		2) Device*group	2.20	0.15
Between subjects factor	Eyes-open	Control - Experimental	1.21	0.28
	Eyes-closed	Control - Experimental	1.22	0.28

In these studies, the data for lateral velocity of sway in the eyes-open condition for control and experimental stroke subjects were similar to those recorded for the healthy elderly subjects described earlier. In contrast, in the eyes-closed condition, the values recorded for the stroke subjects were slightly lower than for the healthy subjects.

These data provide no statistically significant evidence that DAFOs influence the velocity of sway either in the a-p or lateral directions compared to when using casual shoes. However, it is notable that the lateral velocity of sway values are lower between the control and the experimental group. These lower values could suggest a more stable standing position when the splint is used. This, and other circumstantial evidence gained from the balance measurements is discussed later.

3.2.1.4 Sway index

The variability (SD) of the position of the CoP as a function of time indicates the variability of the location of the ground reaction force relative to the feet, and was used as a measure of the stability of subjects while standing. The SD of sway was calculated from the mean of the total CoP measurement from the recording time (30 s) whilst each subject stood still on a force plate and was used as an index of the amount of sway during quiet standing (Winter, 1995; Niam *et al.*, 1999; Wooley, 2001). Lower sway index values are considered to reflect a more steady standing position, implying better balance in both young and elderly adults with normal health (Pushpangadan *et al.*, 1999).

Sway index in a-p direction: eyes-open condition

In the control group, the sway index for the baseline test was 5.26 (1.35), mean and SD. For the second and third tests, the sway indices were similar to the baseline test, at 4.94 (1.66) and 5.24 (1.83), respectively. In the experimental group, under two different conditions (using shoes alone and then using DAFOs) the baseline body sway was

slightly higher compared to the control group, at 6.01 (1.98) with shoes and 5.73 (1.69) with DAFOs. For the second tests, body sway stayed higher than for the control group: 5.38 (1.73) with shoes and 5.38 (0.91) with DAFOs. During the third tests, the values were comparable to the control group; 4.94 (1.37) with shoes and 5.32 (1.56) with DAFOs. The healthy elderly subjects' sway index with eyes-open was 4.54 (0.51).

Sway index in a-p direction: eyes-closed condition

In the control group, the body sway index in the eyes-closed condition for the baseline test was 5.67 (2.24). The second and third tests' sway indices increased to 5.81 (1.68) and 6.09 (2.31), respectively. In the experimental group, baseline a-p sway indices were higher in comparison to the control group, at 7.43 (1.58) using shoes and 6.89 (1.77) using DAFOs. Higher values were also recorded during the second test compared to the control group's second measurement, 6.22 (1.53) with shoes and 7.39 (1.79) with DAFOs. In contrast, for the third test, body sway values were similar to the control group, 6.10 (1.47) with shoes and 6.35 (1.60) with DAFO. The mean and SD for the a-p body sway of the CoP data recorded for control and experimental groups in the each of the tests and under the two experimental conditions are summarized in Figure 3.6. The healthy subjects' sway index was clearly lower at 4.41 (0.67).

Statistical comparisons (ANOVA) within- and between-groups were carried out as described previously. No statistically significant differences were found; the results (*f* and *p* values) for these analyses are summarised in Table 3.16 a. It was noted that in the a-p direction with eyes open, an increase with near borderline statistical significance ($p > 0.08$) was identified for the within subject comparison, using 'time by group' as the within subjects factor in the experimental group. However, this may simply be due to lower variability about the mean values seen within the experimental group over the three tests.

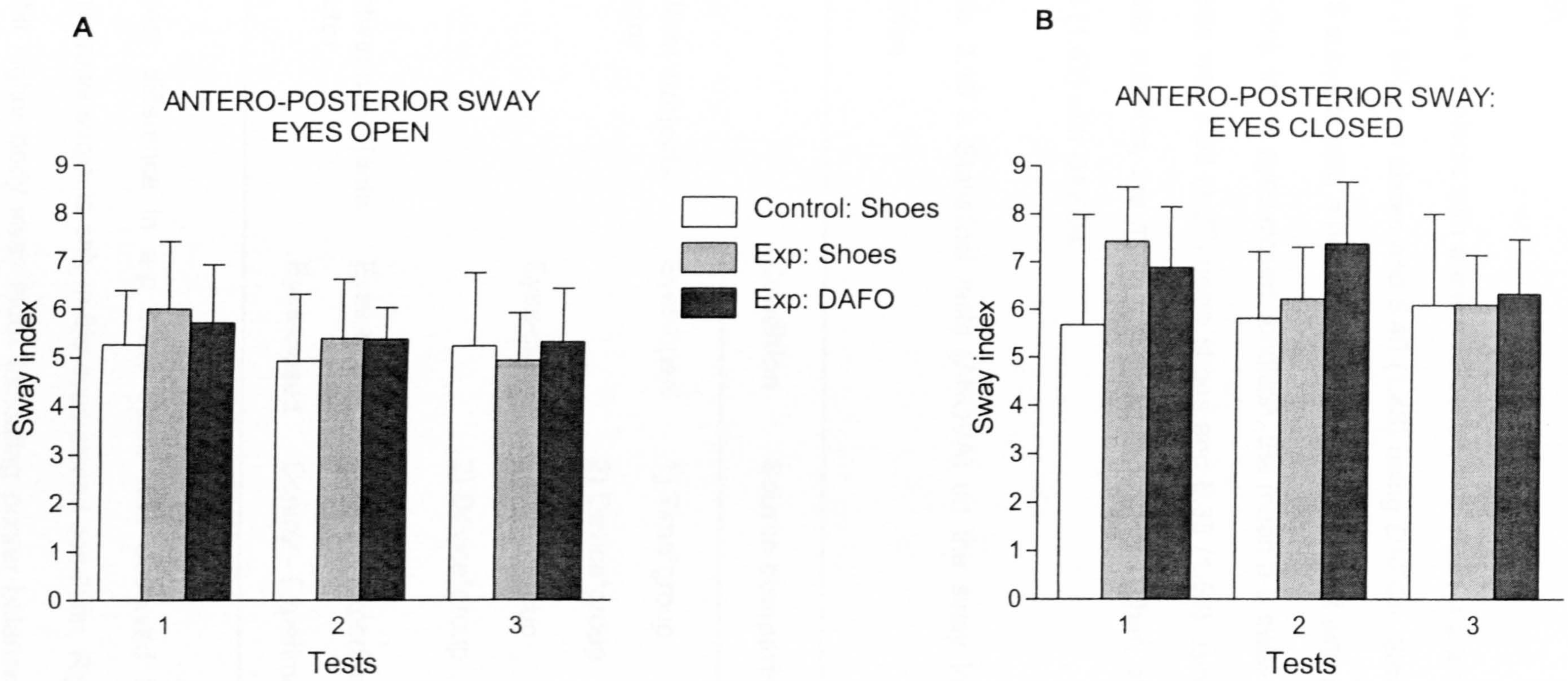


Figure 3.6 Body sway in antero-posterior direction calculated from the SD of the displacement of CoP (sway index). Tests were carried out with eyes open (A) and eyes closed (B). Control subjects (n = 8) were tested wearing their own shoes. Experimental subjects (n = 10) were tested separately with their shoes and when wearing DAFOs. Measurements for all subjects were recorded on the 3 testing sessions as described in Methods. Data are mean and SD.

In these investigations, the stroke subjects presented higher CoP sway indices values in the a-p direction than those presented earlier for the healthy elderly subjects and as reported elsewhere (Briggs *et al.*, 1989; Winter, 1991b; Era *et al.*, 1996; Niam *et al.*, 1999).

For the 5 subjects with a left side deficit, the mean a-p sway index with eyes-open was 5.85 (1.94) with shoes and 5.40 (1.43) using DAFOs. Similar values were recorded for the 5 subjects with a right side deficit (5.04 SD 0.62 with shoes and 5.55 SD 1.34 with DAFOs). In the eyes-closed condition, the mean a-p sway for the subjects with left side paresis was 6.53 (1.27) using shoes and 6.38 (1.56) using DAFOs; for the right sided paretic subjects, the mean values were slightly higher, at 6.64 (1.45) with shoes and 7.38 (1.42) with DAFOs.

Table 3.16 a Statistical tests (ANOVA) on the sway index for the CoP in the a-p direction

	Condition	Source comparison	*f*	*p*
Within subjects factor	Eyes-open	1) Time*group	3.37	0.08
		2) Device*group	0.16	0.19
	Eyes-closed	1) Time*group	2.71	0.11
		2) Device*group	0.09	0.75
Between subjects factor	Eyes-open	Control - Experimental	0.77	0.39
	Eyes-closed	Control - Experimental	1.54	0.24

A clear difference in a-p sway index was observed between left and right side hemiparesis subjects only in the eyes-closed condition. Right side hemiparesis subjects exhibit higher body sway index indicating poorer balance than on their left side. This

difference did not achieve statistical significance. No effects in a-p sway index were evident using DAFOs compared using shoes alone for both left or right side paresis subjects.

Sway index in lateral direction: eyes-open condition

When measured in the lateral direction, the control group sway index in the *eyes-open* condition for the baseline test was 4.27 (2.31), mean and (SD). In For the second and third tests, the sway values recorded were clearly lower compared to the baseline test, at 3.74 (2.23) and 2.89 (1.18), respectively. In the experimental group, the lateral sway indices for the baseline test were 4.90 (3.09) with shoes and 4.36 (2.31) with DAFOs. In the second test and third tests the values recorded were 3.68 (2.17), 4.16 (2.59) and 3.85 (1.86), 3.39 (1.77) with shoes and DAFOs, respectively. Thus, when wearing DAFOs, the body sway indices for the control and experimental groups decreased from the baseline test to the third test (Figure 3.7 A). However, slightly higher sway indices were seen in the experimental group compared to the control group, particularly in the baseline and third tests. Under the same condition, it was determined that the healthy subjects sway index was 2.51 (0.57).

Sway index in lateral direction: eyes-closed condition

The control group lateral sway index in the eyes-closed condition was 3.88 (1.61), mean and (SD). Slightly higher mean values were recorded during the second (mean 3.99, SD 1.76) and third (mean 4.17, SD 2.02) tests. In the experimental group, the mean lateral sway indices for the baseline test were substantially higher than for the control group, at 6.26 (3.11) using shoes and 5.26 (2.91) using DAFOs. The second test values recorded were 4.35 (2.14) with shoes and 4.51 (2.31) with DAFOs. In the third test the values were 4.82 (2.61) with shoes and 4.49 (2.46) with DAFOs. The control group presented clearly lower lateral sway indices compared to the experimental group (see Figure 3.7

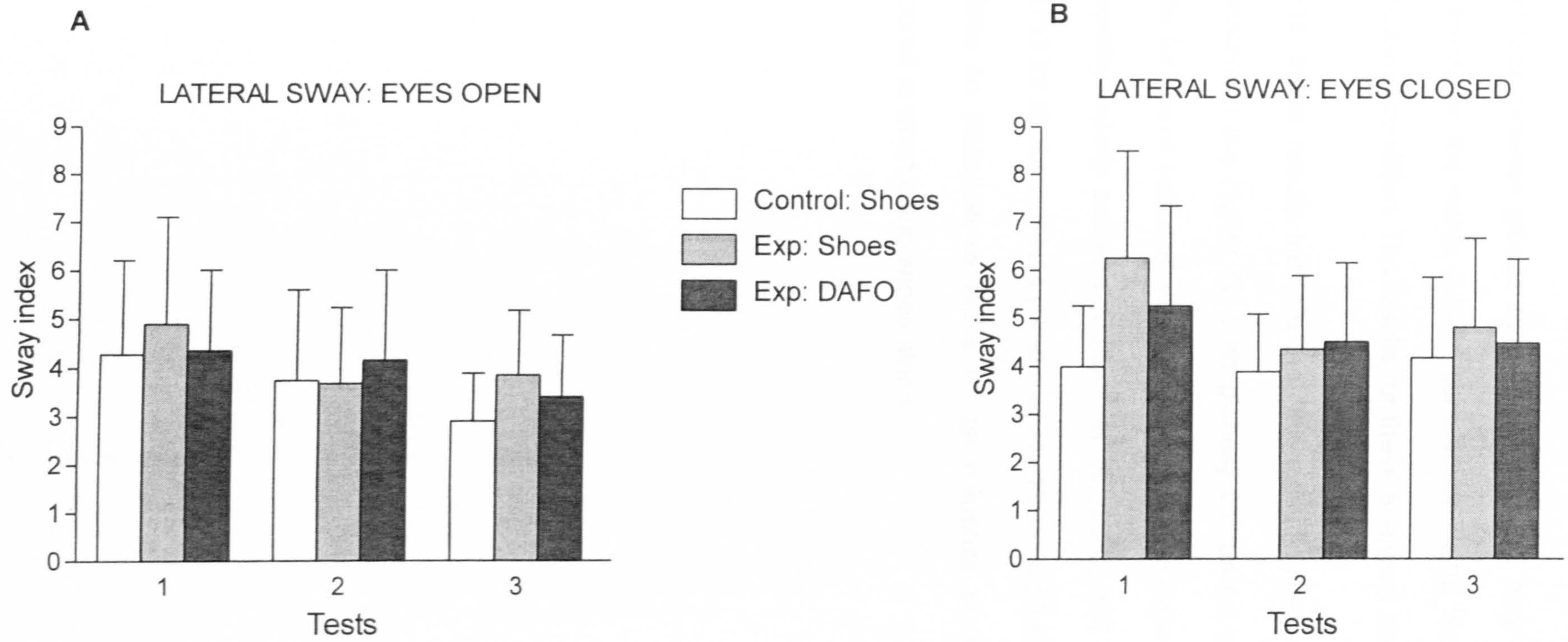


Figure 3.7 Body sway in lateral direction calculated from the SD of the displacement of CoP (sway index). Tests were carried out with eyes open (A) and eyes closed (B). Control subjects (n = 8) were tested wearing their own shoes. Experimental subjects (n = 10) were tested separately with their shoes and when wearing DAFOs. Measurements for all subjects were recorded on the 3 testing sessions as described in Methods. Data are mean and SD.

B). The measurements made on healthy subjects in the eyes-closed condition provided values of 3.04 (0.87), mean and (SD).

Statistical comparisons were performed as described earlier; no statistically significant differences between groups were found, although near borderline difference (p = 0.07) was found for the within subject comparison using 'time by group' as a factor in the *eyes-closed* condition. The results for these analyses are summarised in Table 3.16 b.

Overall, these results indicate that the sway indices of stroke patients (control and experimental) are higher (in both planes) compared to healthy elderly subjects. The results for stroke subjects' sway indices presented here are higher than reported earlier for healthy elderly subjects (Pollack *et al.*, 2002) but are similar to those previously reported for stroke subjects (Goldie *et al.*, 1996; Walker *et al.*, 2000). The present work provides no statistical evidence for an influence of the DAFO on CoP sway index compared to when using shoes alone.

Table 3.16 b Statistical tests (ANOVA) on the sway index for the CoP in the lateral direction

	Condition	Source comparison	*f*	*p*
Within subjects factor	Eyes-open	1) Time*group	0.03	0.85
		2) Device*group	1.04	0.32
	Eyes-closed	1) Time*group	3.75	0.07
		2) Device*group	0.90	0.35
Between subjects factor	Eyes-open	Control - Experimental	0.11	0.74
	Eyes-closed	Control - Experimental	1.18	0.29

For the left side paretic subjects, the mean lateral sway indices with eyes-open were 4.44 (2.57) with shoes and 4.10 (2.37) using DAFOs. For the subjects with right side paresis, lateral sway was slightly lower, at 3.84 (1.83) with shoes and 3.84 (1.93) with DAFOs. In the eyes-closed condition, subjects with left side paresis presented mean lateral sway values of 4.82 (2.63) using shoes and 4.20 (2.35) with DAFOs. For the subjects with right side paresis the mean values were higher, at 5.47 (2.06) with shoes and 5.31 (2.42) with DAFOs. Thus, differences in lateral sway indices were evident between left and right side hemiparesis subjects in both eyes-open (left side indicates unsteady balance) and eyes-closed (right side indicates unsteady balance) conditions. In these tests, DAFOs induced no discernable effects on subjects' lateral sway compared to using shoes alone.

3.2.1.5 Spectral frequency of horizontal forces

The horizontal forces applied to the surface of the platform, Fx and Fz, were measured to further assess subjects' balance. These horizontal (shear) forces were used because they describe the acceleration of the centre of mass. Such acceleration represents the vibrations of the centre of mass of the body (spectral characteristic of the postural control) and may provide a more sensitive measure than CoP excursion data for identifying difficulties with balance (section 2.4.1). Fz and Fx are calculated using the spectral frequency of the central tendency of the power spectra (Liu and Lawson, 1995; McClenaghan *et al.*, 1995).

Mean spectral frequency

F(mean) of the spectral frequency was calculated (equation in Appendix IV) and used to define the centroid of the spectrum (McClenaghan *et al.*, 1995). Earlier studies have demonstrated that lower mean values for spectral frequency are associated with poorer control of balance in elderly and young healthy adults and several disabilities

(McClenaghan *et al.*, 1995; Nadeau *et al.*, 1999b). Higher values are believed to reflect steadier postural balance (McClenaghan *et al.*, 1995).

F(mean) in the a-p plane: eyes-open condition

In the control group, the spectral frequency during the baseline test was 1.73 Hz (0.32). For the second and third tests the values recorded were lower than for the baseline test, at 1.63 Hz (0.53) and 1.42 Hz (0.43), respectively. In the experimental group, the baseline mean spectral frequency values were lower than for the control group, at 1.70 Hz (0.43) using shoes and 1.59 Hz (0.52) using DAFOs. In the second test, body sway remained lower than that of the control group (1.53 Hz SD 0.25 with shoes and 1.59 Hz SD 0.28 with DAFOs). During the third test, the values were higher than for the control group measurements (1.54 Hz SD 0.22 with shoes and 1.59 Hz SD 0.37 with DAFOs). The comparative values for the healthy elderly subjects in same condition was 1.54 Hz (0.29), mean and SD.

F(mean) in the a-p plane: eyes-closed condition

The mean spectral frequency for the control group, the baseline test was 1.58 Hz (0.38). The frequency during the second test increased to 1.65 Hz (0.40) and then decreased to 1.51 Hz (0.56) during the third test. In the experimental group, the mean spectral frequencies were higher than for the control group, particularly during the baseline measurements (1.70 Hz, SD 0.36 using shoes and 1.69 Hz, SD 0.20 using DAFOs) and third tests (1.60, SD 0.21 using shoes and 1.76, SD 0.36 using DAFOs). The values for the second test were closer to control levels (1.67, SD 0.37 using shoes and 1.72, SD 0.24 using DAFOs). For the healthy subjects in the eyes-closed condition the F(mean) was 1.69 Hz (0.39), mean and (SD).

The mean and SD for the mean spectral frequencies recorded for the control and experimental groups in each of the tests, with eyes-open and eyes-closed, are summarized in Figure 3.8. No statistically significant differences were observed. The *f*

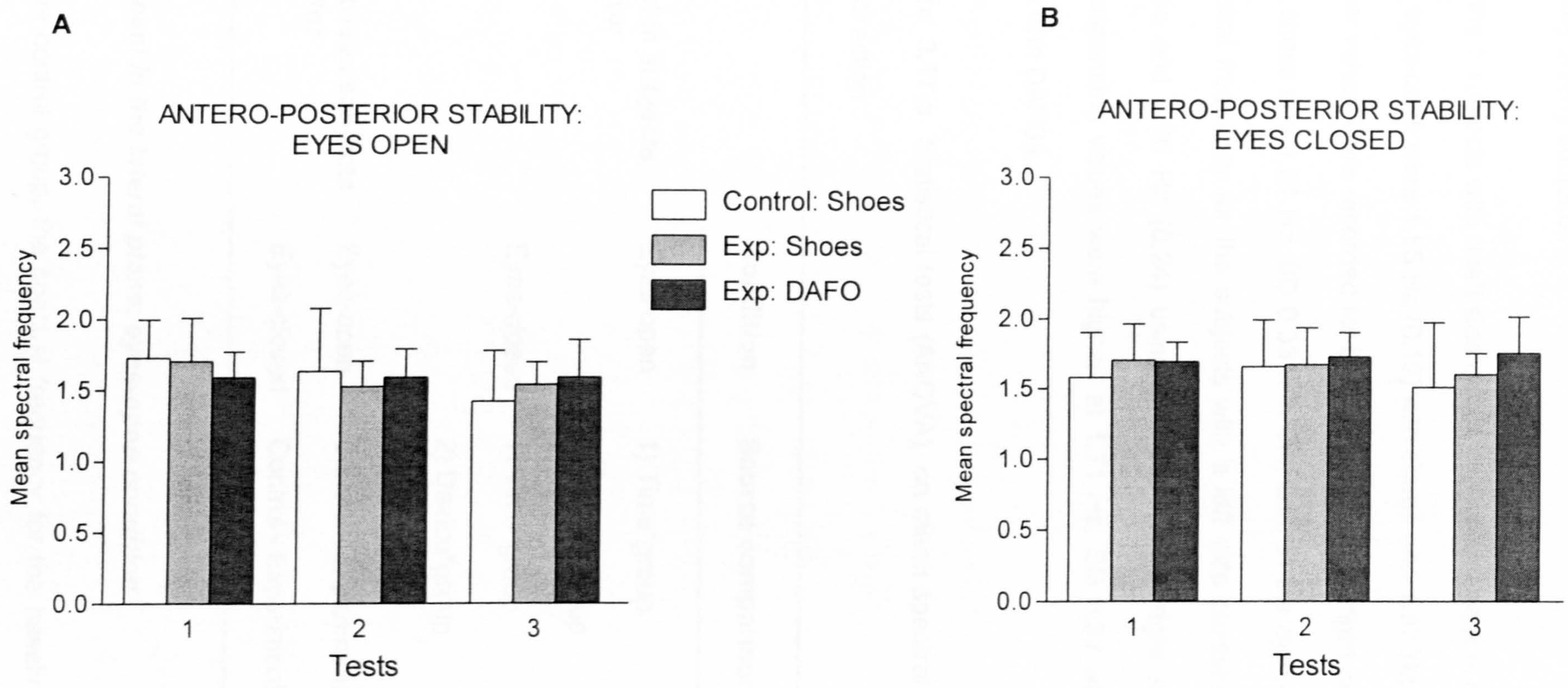


Figure 3.8 Mean spectral frequency expressed as postural stability calculated from the shear forces in the antero-posterior plane. Tests were carried out with subjects' eyes open (A) and eyes closed (B). Control subjects (n = 8) were tested wearing their own shoes. Experimental subjects (n = 10) were tested separately with their shoes and when wearing DAFOs. Measurements for all subjects were recorded on the 3 testing sessions as described in Methods. Data are mean and SD.

and *p* values for these analyses are summarised in Table 3.17 A. For both stroke groups, the recordings of mean spectral frequencies were comparable to those of healthy elderly subjects.

For the 5 subjects with a left side deficit, the mean spectral frequencies in the a-p plane with eyes-open were 1.55 Hz (0.19) with shoes and 1.57 Hz (0.25) with DAFOs. Slightly higher values were recorded for the 5 subjects with a right side deficit (1.63 Hz, SD 0.28 with shoes and 1.61 Hz, SD 0.33 with DAFOs). In the eyes-closed condition, the mean spectral frequency for the subjects with a *left* side paresis was 1.61 Hz (0.19) using shoes and 1.66 Hz (0.24) using DAFOs; for the right sided paresis subjects, the corresponding values were higher, at 1.71 Hz, SD 0.32 with shoes and 1.79 Hz, SD 0.18 with DAFOs.

Table 3.17 a Statistical tests (ANOVA) on mean spectral frequency [F(mean)] in the a-p direction

	Condition	Source comparison	*f*	*p*
Within subjects factor	Eyes-open	1) Time*group	1.09	0.31
		2) Device*group	0.40	0.53
	Eyes-closed	1) Time*group	0.05	0.82
		2) Device*group	0.97	0.33
Between subjects factor	Eyes-open	Control - Experimental	0.02	0.87
	Eyes-closed	Control - Experimental	0.04	0.82

F(mean) in the lateral plane: eyes-open condition

In the control group, the spectral frequency for the baseline test was 1.91 Hz (0.47). During the second and third tests, the lateral spectral frequency values increased to

2.33 Hz (0.72) and 2.20 Hz (0.51), respectively. In the experimental group the mean spectral frequency in the lateral plane for the baseline test was 1.92 Hz (0.53) using shoes and 2.02 Hz (0.53) using DAFOs. In the second and third tests, the corresponding values were: 1.92 Hz (0.35), 2.17 Hz (0.53) and 1.89 Hz (0.30), 1.92 Hz (0.41). Thus, the mean spectral frequency remained close to baseline levels (Figure 3.9 A). However, the control group presented slightly higher mean lateral frequencies in the eyes-open condition than the experimental group, particularly in the second and third tests. Higher values are believed to reflect steadier postural balance (McClenaghan *et al.*, 1995; Nadeau *et al.*, 1999b). In the lateral direction, with eyes-open, the mean spectral frequency for the healthy elderly subjects was recorded at 1.89 Hz (0.36), mean and (SD).

F(mean) in the lateral plane: eyes-closed condition

For the control group, the F(mean) spectral frequency in the eyes-closed condition for the baseline test was 2.23 Hz (0.35), and similar values were obtained for the second (mean 2.19 Hz, SD 0.69) and third (mean 2.38 Hz, SD 0.44) tests. In the experimental group, the lateral mean spectral frequencies for the baseline test were 2.12 Hz (0.45) using shoes and 1.81 Hz (0.39) using DAFOs. During the second tests, the values recorded were also lower (1.81 Hz, SD 0.42 with shoes and 1.88 Hz, SD 0.35 with DAFOs) compared to the control group. Similarly, the mean spectral frequency values obtained for the third test (2.03 Hz, SD 0.35 with shoes and 2.03 Hz, SD 0.37 with DAFOs) remained lower compared to the control group. The control group presented higher F(mean) values than the experimental group throughout all three tests over the 12 weeks testing period (Figure 3.9 B). Statistical comparisons within- and between-groups were carried out; no statistically significant differences were identified (Table 3.17 b). Comparative data for healthy subjects F(mean) in the eyes-closed condition was 1.97 Hz (0.37), mean and (SD).

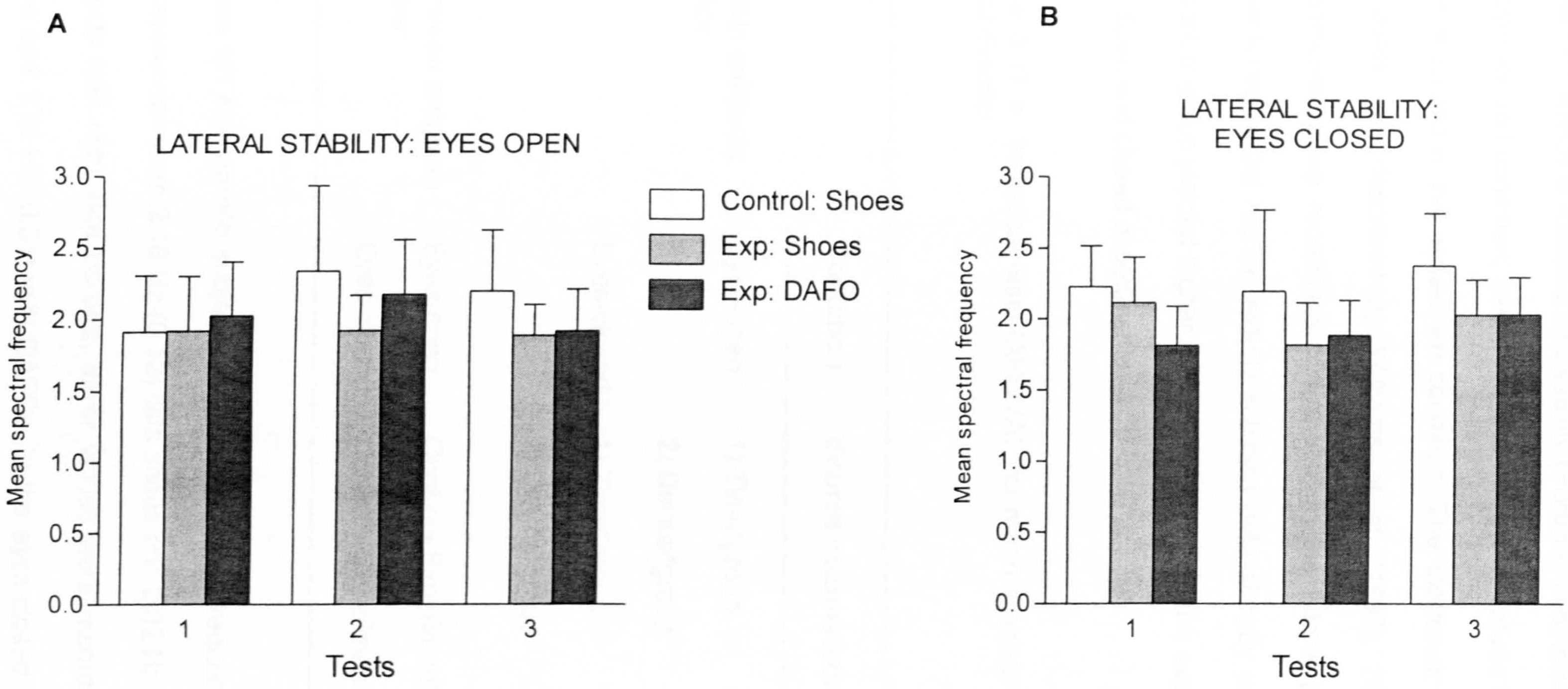


Figure 3.9 Mean spectral frequency expressed as postural stability calculated from the shear forces in the medial-lateral plane. Tests were carried out with subjects' eyes open (A) and eyes closed (B). Control subjects (n = 8) were tested wearing their own shoes. Experimental subjects (n = 10) were tested separately with their shoes and when wearing DAFOs. Measurements for all subjects were recorded on the 3 testing sessions as described in Methods. Data are mean and SD.

Earlier studies have shown that lower F(mean) spectral frequency in the lateral plane can identify balance unsteadiness for elderly healthy individuals (Williams *et al.*, 1997) and when balance is affected by disability (Portfors-Yeomans and Riach, 1995). Here, in the eyes-closed condition, mean spectral frequency values were indistinguishable from those recorded in the eyes-open condition. The existence of this situation for elderly individuals was described by Williams *et al.* (1997). In the current studies, the experimental group recordings of F(mean) in the lateral plane were found to be at similar levels to the healthy elderly subjects data already presented (section). Overall, the control group yielded higher F(mean) values than the experimental group in both the eyes open and closed experiments.

Table 3.17 b Statistical tests (ANOVA) for mean spectral frequency [F(mean)] in the lateral direction

	Condition	Source comparison	*f*	*p*
Within subjects factor	Eyes-open	1) Time*group	0.33	0.57
		2) Device*group	1.11	0.30
	Eyes-closed	1) Time*group	0.04	0.83
		2) Device*group	0.18	0.67
Between subjects factor	Eyes-open	Control - Experimental	0.86	0.36
	Eyes-closed	Control - Experimental	3.42	0.83

For the left side paretic subjects the mean spectral frequencies in the lateral direction with eyes-open were 2.18 Hz (0.12) with shoes and 2.32 Hz (0.19) with DAFOs. For the subjects with right side paresis, lower values were recorded, at 1.64 Hz (0.21) with shoes and 1.72 Hz (0.34) with DAFOs. In the eyes-closed condition, subjects with left side paresis presented spectral frequency values of 2.17 Hz (0.17) using shoes and

2.03 Hz (0.23) with DAFOs. For the subjects with right side paresis the values recorded were lower, at 1.80 Hz (0.32) with shoes and 1.78 Hz (0.15) with DAFOs. Thus, differences in lateral spectral frequencies were evident between left and right side hemiparesis subjects; in both the eyes-open and eyes-closed conditions, the right side hemiaptetic subjects indicated lower values than those with a left side deficit. DAFOs induced no discernable effects on experimental subjects' mean spectral frequencies compared to using shoes alone.

3.2.1.6 Distribution of spectral energy (variability)

To measure the distribution of energy of the power spectra, the variability (sd) of the power spectra was used to quantify the frequency distribution. Higher sd indicates less control of balance in healthy subjects (Nadeau *et al.*, 1999b).

Variability in the a-p plane: eyes-open condition

In the control group, the spectral frequency in the a-p direction with eyes-open for the baseline test was 0.71 Hz (0.19), mean and SD. Similar data were recorded for the second (mean 0.69 Hz, SD 0.15) and third (mean 0.71 Hz, SD 0.13) tests. In the experimental group, the values obtained for baseline measurements of spectral frequency variability were lower compared to the control group, at 0.7 Hz (0.12) and 0.63 Hz (0.13), respectively. The values for the second test (0.63 Hz, SD 0.15 with shoes and 0.66 Hz, SD 0.16 with DAFOS) and third test (0.66 Hz, SD 0.16 with shoes and with 0.64 Hz, SD 0.14 with DAFOs) remained slightly lower than for the control group. The variability of the spectral frequencies with eyes-open for both control and experimental groups were lower than for the healthy elderly subjects (0.77 Hz, SD 0.15, n = 4). As higher F(sd) spectral frequency may also be indicative of balance unsteadiness (Williams *et al.*, 1997), it is unclear why the healthy subject data provided somewhat higher variability of the spectral frequency values that of the stroke subjects. A possible explanation for this unexpected observation is that the former did not (or

were unable to) concentrate fully during the testing procedures. Alternatively, the limited number of subjects used in the present studies may account for this discrepant finding.

Variability in the a-p plane: eyes-closed condition

Measurements of spectral frequency variability in the control group with eyes-closed for the baseline test was 0.66 Hz (0.1), mean and (SD). The values recorded for the second test were unchanged (0.66 Hz, SD 0.29), but increased slightly during the third test (0.7 Hz, SD 0.15). In the experimental group, with shoes and then with DAFOs, the values for spectral frequency variability were: baseline test, 0.62 Hz, (0.1) and 0.62 Hz (0.11); second test, 0.6 Hz (0.17) and 0.6 Hz (0.13); third test, 0.59 Hz (0.11) and 0.65 Hz (0.14). Thus, in the eyes-open condition, the values for experimental subjects' frequency variability were consistently lower than the control group throughout the three tests, both with shoes and with DAFOs. The mean and SD for the variability of the spectral frequency measurements recorded for the control and experimental groups in the each of the tests and under the two experimental conditions are summarized in Figure 3.10. No statistically significant differences were found; *f* and *p* values are summarised in Table 3.18 a. The healthy subjects yielded a value of 0.77 Hz (0.16), mean and (SD).

For the 5 subjects with a left side deficit, the variability of the spectral frequency in the a-p plane with eyes-open was 0.68 Hz (0.07) with shoes and 0.66 Hz (0.11) with DAFOs. Slightly lower values were recorded for the 5 subjects with a right side deficit (0.65 Hz, SD 0.09 with shoes and 0.63 Hz, SD 0.16 with DAFOs). In the eyes-closed condition, the values of the spectral frequency variabilities for the subjects with left side paresis stayed slightly higher than the right sided paretic subjects (see Table 3.20).

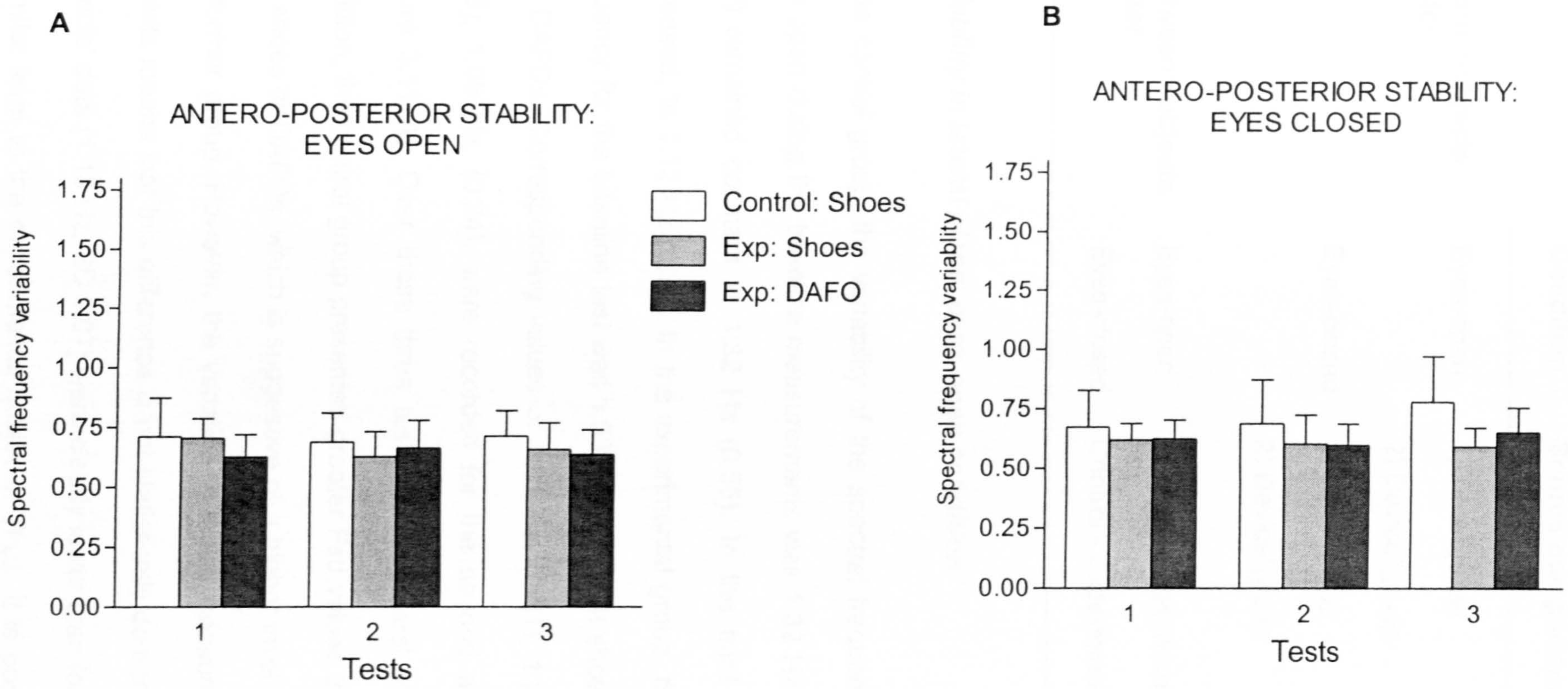


Figure 3.10 Variability of the spectral frequency distribution in the antero-posterior plane. Tests were carried out with subjects' eyes open (A) and eyes closed (B). Control subjects (n = 8) were tested wearing their own shoes. Experimental subjects (n = 10) were tested separately with their shoes and when wearing DAFOs. Measurements for all subjects were recorded on the 3 testing sessions as described in Methods. Data are mean and SD.

Table 3.18 a Statistical tests (ANOVA) for variability of the spectral frequency [F(sd) in a-p direction

	Condition	Source comparison	*f*	*p*
Within subjects factor	Eyes-open	1) Time*group	1.38	0.25
		2) Device*group	0.42	0.52
	Eyes-closed	1) Time*group	0.08	0.78
		2) Device*group	0.22	0.64
Between subjects factor	Eyes-open	Control - Experimental	1.24	0.28
	Eyes-closed	Control - Experimental	1.15	0.29

Variability in lateral plane: eyes-open condition

In the control group, the variability of the spectral frequency in the lateral plane with eyes open during the baseline measurements was 1.32 Hz (0.45). In the second test, F(sd) remained constant at 1.32 Hz (0.55). In the third test, the variability clearly decreased, to 1.12 Hz (0.29). In the experimental group, the variability of the spectral frequency for the baseline test was 1.03 Hz (0.4) with shoes alone and 1.13 Hz (0.41) with DAFOs. Corresponding values of 1.01 Hz, (0.31), 1.22 Hz, (0.54) and 1.08 Hz, (0.28), 1.05 Hz, (0.34), were recorded for the second and third tests, respectively (Figure 3.11 A). Over these three tests, in the lateral plane and in the *eyes-open* condition, the control group presented greater Fsd values than the experimental group, with shoes or DAFOs, which is suggestive of a higher level of balance unsteadiness for the former group. However, the variation in these measurements between the stroke subjects means that this difference is not statistically demonstrable. The healthy elderly subjects' data (1.18 Hz, SD 0.07) were clearly lower than for the control subjects, but at a similar level to the experimental subjects. Thus, it is possible that the experimental group's lateral balance was steadier than that of the control group.

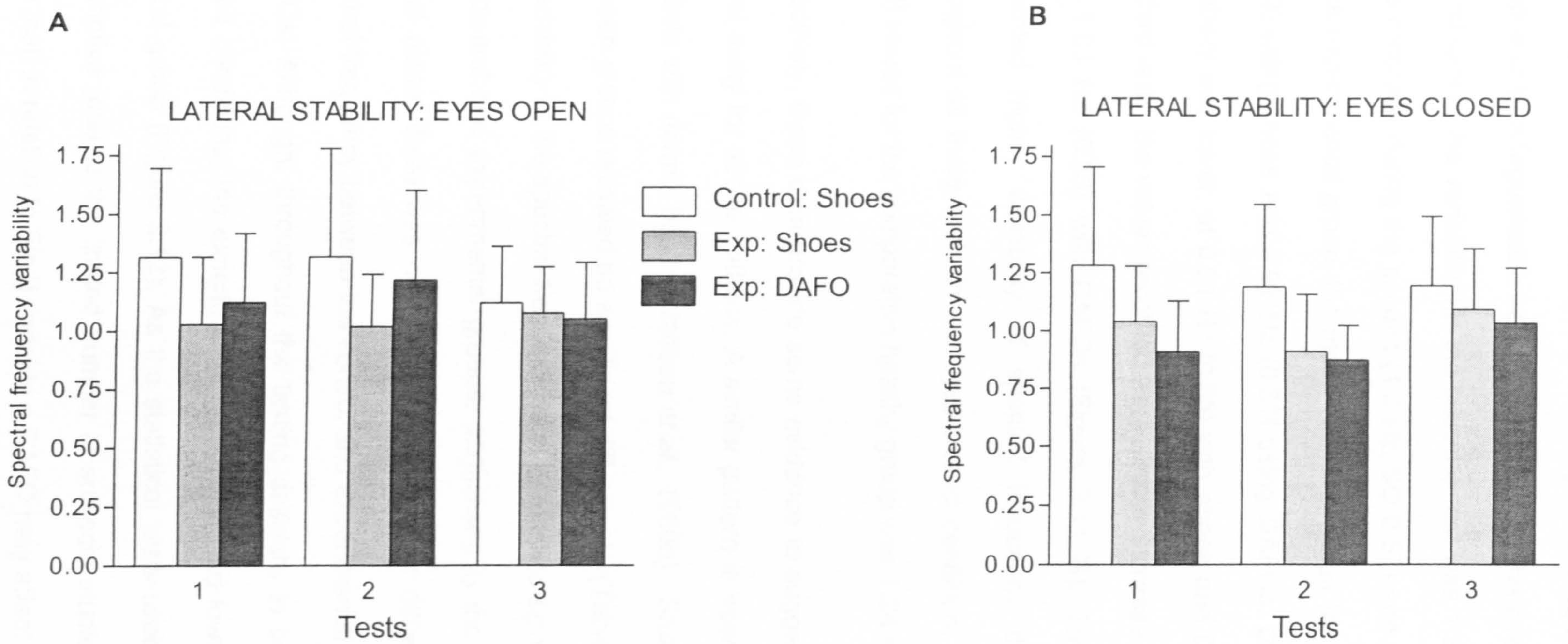


Figure 3.11 Variability of the spectral frequency distribution in the medial-lateral plane. Tests were carried out with subjects' eyes open (A) and eyes closed (B). Control subjects (n = 8) were tested wearing their own shoes. Experimental subjects (n = 10) were tested separately with their shoes and when wearing DAFOs. Measurements for all subjects were recorded on the 3 testing sessions as described in Methods. Data are mean and SD.

Variability in lateral plane: eyes-closed condition

In the *eyes-closed* condition, the variability of the spectral frequency for the control group was indistinguishable from that recorded in the eyes-open condition. Thus, in the control group, the variability for the baseline test was 1.32 Hz (0.39) and similar levels were recorded during the second (1.2 Hz, SD 0.57) and third (1.38 Hz, SD 0.44) tests. In the experimental group, the mean variability value for the baseline test was 1.04 Hz (0.33) using shoes and 0.91 Hz (0.31) using DAFOs. During the second tests, mean variability was lower, at 0.91 Hz (0.35) with shoes and 0.87 Hz (0.21) with DAFOs. In the third tests, the values recorded were slightly increased, to 1.09 Hz (0.37) with shoes and 1.03 Hz (0.33) with DAFOs (Figure 3.11 B). Thus, the control group clearly presented higher variability of spectral frequency than the experimental group throughout all three tests in the eyes-closed condition. In the eyes-closed condition, F(sd) values for the comparative healthy group was 1.24 Hz (0.21).

Collectively, these data provide some evidence to suggest that a-p sway is lower than lateral sway for stroke patients. A similar pattern is seen in younger and elderly adult subjects with normal health (Nadeau *et al.*, 1999b). Statistical comparisons within and between groups revealed no significant differences (Table 3.18 b). However, alterations in variability of the spectral frequency with borderline significance were evident between the control and experimental groups, particularly in the eyes-closed condition. In the lateral plane, there was no statistically significant difference in the variability of the spectral frequency between the control and experimental groups using casual shoes or DAFOs. Although, throughout the testing session, in both the eyes-open and eyes-closed conditions, the experimental group exhibited lower sd values compared to the control group (Figure 3.12). As the statistical tests used in this thesis are essentially descriptive (due to the limited number of subjects studied), it is possible to speculate here that, in relation to F(sd) variable a DAFO may affect the balance of stroke patients, and this effect occurs independently of visual sensory feedback.

Table 3.18 b Statistical tests (ANOVA) for variability of the spectral frequency (Fsd) in the lateral direction

	Condition	Source comparison	*f*	*p*
Within subjects factor	Eyes-open	1) Time*group	0.02	0.88
		2) Device*group	0.88	0.36
	Eyes-closed	1) Time*group	1.03	0.32
		2) Device*group	2.64	0.12
Between subjects factor	Eyes-open	Control - Experimental	1.06	0.31
	Eyes-closed	Control - Experimental	3.35	0.08

The variability of the spectral frequencies in the lateral plane with eyes-open and closed was slightly higher than that recorded for healthy elderly subjects, a profile that was particularly evident for the control group.

For the left side paretic subjects, the mean value of the SD of the spectral frequency from the three tests with eyes-open was 1.23 Hz (0.26) with shoes and 1.33 Hz (0.33) using DAFOs. For the subjects with right side paresis the mean value of the SD was slightly lower, at 0.86 Hz (0.13) with shoes and 0.93 Hz (0.27) with DAFOs. In the eyes-closed condition, subjects with left side paresis presented values of 1.15 Hz (0.31) using shoes and 1.03 Hz (0.28) with DAFOs. For the subjects with right side paresis the SD values were again lower, at 0.88 Hz (0.27) with shoes and 0.84 Hz (0.18) with DAFOs. Thus, differences in the SD of the spectral frequency were evident between left and right side hemiparesis subjects in both eyes-open and eyes-closed (left side indicating poorer balance) conditions.

3.2.1.7 Slope of spectral frequency distribution

The slope of the spectral frequency distribution [F(slope)] is calculated from a double log axis plot of the power spectrum (following the equation presented in Appendix IV). Progressively negative F(slope) values represent increasing loss of high frequencies within the spectra, which is associated with poorer balance in healthy elderly subjects who, according to their medical history, are categorised as at high-risk for stroke (Nadeau *et al.*, 1999b).

F(slope) in the a-p plane: eyes-open condition

In the control group, F(slope) of the spectral frequencies for the baseline test, in the a-p direction with subjects' eyes-open was -1.45 (0.19). In the second and third tests the F(slope) values recorded were substantially increased, at -1.67 (0.22) and -1.80 (0.34), respectively. In the experimental group, the baseline F(slope) values were found to be more negative than the control group, at -1.60 (0.30) with shoes and -1.69 (0.21) with DAFOs. The corresponding values determined for the second and third tests were -1.67 (0.21), -1.62 (0.15) and -1.78 (0.36), -1.69 (0.22). Thus, F(slope) within the experimental group yielded a more negative slope when wearing DAFOs than when using shoes alone (particularly in the baseline test, but not in the second and third tests). In the healthy elderly subjects, the corresponding F(slope) values recorded in the a-p direction with subjects' eyes-open was -1.57 (0.15), mean and SD.

F(slope) in the a-p plane: eyes-closed condition

In the eyes-closed condition, the F(slope) values of the control group in the a-p plane, F(slope) for the baseline test was -1.74 (0.27), mean and (SD). In comparison, the F(slope) recorded for the second test was slightly increased, at -1.82 (0.38), whereas in the third test the value was clearly lower, at -1.59 (0.25). In the experimental group, the F(slope) baseline tests were similar level to that recorded for the control group (-1.63,

SD 0.2 using shoes and -1.73, SD 0.29 using DAFOs). During the second tests the F(slope) values were -1.72 (0.25) and -1.68 (0.19), respectively. During the third tests, a similar change in the magnitude of F(slope) level was observed, but in the opposite direction to that seen in the second tests (-1.71, SD 0.17 using shoes and -1.70, SD 0.38 using DAFO). It is noted that the variation overlap of these measurements means that these observations are tentative. In the eyes-closed condition, the F(slope) value of the healthy subjects was less negative at -1.57 (0.21).

Within the experimental group, F(slope) was greater when subjects wore shoes compared to when using DAFOs , an effect that was seen in the second and third tests. The results for these studies are summarized in Figure 3.12. Statistical comparisons within and between groups were carried out as described earlier; no significant differences were found (Table 3.19 a). The magnitudes of these F(slope) values (control and experimental group data) are lower than the measurements made on healthy elderly subjects, which is in accord with earlier studies (McClenaghan *et al.*, 1995).

For the 5 subjects with left side hemiparesis, the F(slope) with eyes-open in the a-p plane was -1.64 (0.12) using shoes and -1.67 (0.15) using DAFOs. Marginally steeper values were recorded for the 5 subjects with a right side deficit (-1.72, SD 0.15 with shoes and -1.66, SD 0.15 with DAFOs). In the eyes-closed condition, the F(slope) for the subjects with left side paresis was -1.63, SD 0.08 using shoes and -1.63, SD 0.17 using DAFOs; for the subjects with right side paresis the F(slope) was slightly greater, at -1.75, SD 0.11 with shoes and -1.75 SD, 0.24 with DAFOs.

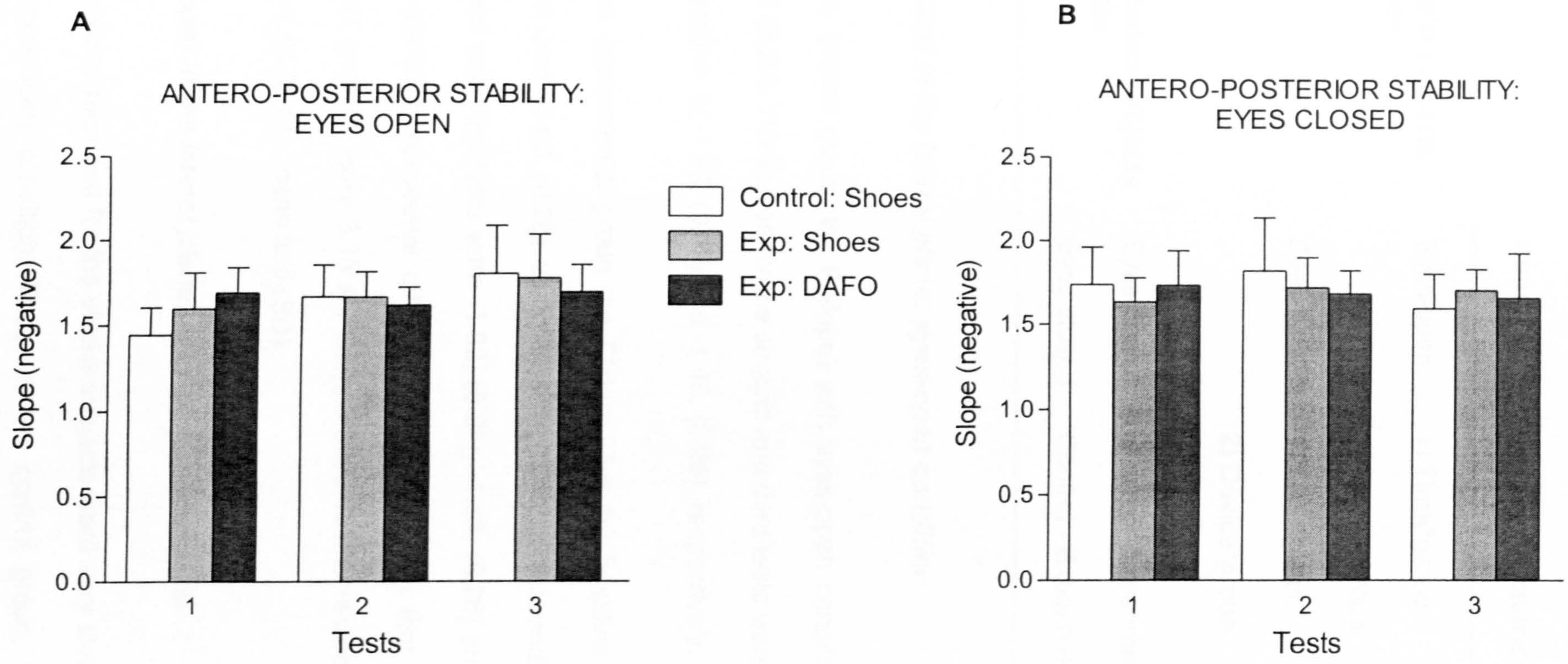


Figure 3.12 Slope of the spectral frequency distribution in the antero-posterior plane. Tests were carried out with subjects' eyes open (A) and eyes closed (B). Control subjects (n = 8) were tested wearing their own shoes. Experimental subjects (n = 10) were tested separately with their shoes and when wearing DAFOs. Measurements for all subjects were recorded on the 3 testing sessions as described in Methods. Data are mean and SD.

Table 3.19 a Statistical tests (ANOVA) for the slope of the spectral frequency distribution [F(slope)] in the a-p direction

	Condition	Source comparison	*f*	*p*
Within subjects factor	Eyes-open	1) Time*group	0.05	0.82
		2) Device*group	0.03	0.85
	Eyes-closed	1) Time*group	0.56	0.46
		2) Device*group	1.19	0.29
Between subjects factor	Eyes-open	Control - Experimental	0.41	0.53
	Eyes-closed	Control - Experimental	0.29	0.59

F(slope) in the lateral plane: eyes-open condition

In the control group, the F(slope) with eyes-open condition for the baseline test was -1.84 (0.20). The values for the second and third tests were clearly less steep compared to baseline, at -1.44, (0.19) and -1.46, (0.26), respectively.

In the experimental group the F(slope) for the baseline test was -1.68 (0.40) using shoes and -1.60 (0.28) using DAFOs. The corresponding values recorded for the second and third tests were -1.62, (0.28), -1.48, (0.26) and -1.66, (0.25), -1.73, (0.34), and therefore somewhat different (more negative) that the F(slope) values for the control group (Figure 3.13 A). Comparative values recorded with the healthy subjects was -1.64 (0.43), mean and (SD).

F(slope) in the lateral plane: eyes-closed condition

The values recorded for the stroke subjects were very similar to those measured under the eyes-open condition. Thus, in the control group, the values for the baseline assessments were -1.56, SD 0.28 (test 1), -1.69, SD 0.3 (test 2) and -1.38, SD 0.21

(test 3). In the experimental group, the F(slope) for the baseline test was -1.55 (0.28) using shoes and -1.76 (0.26) using DAFOs. During the second test, the values were -1.76 (0.37) with shoes and -1.67 (0.32) with DAFOs. In the third test, a small decrease in F(slope) was evident (-1.56, SD 0.23 with shoes and -1.58, SD 0.22 with DAFOs) compared to the earlier tests (Figure 3.13 B). Thus, the control group presented less negative F(slope)s values than the experimental group throughout all three tests in the *eyes-closed* condition. In the eyes-closed condition, the F(slope) for the healthy subjects was -1.55 (0.17).

The routine statistical comparisons revealed no significant difference throughout the testing period (Table 3.19 b). The F(slope) values for the stroke subjects were slightly more negative to those measured with healthy elderly subjects. It is noted that the magnitude of these control values are somewhat more negative than was reported earlier (Nadeau *et al.*, 1999b).

Table 3.19 b Statistical tests (ANOVA) for the slope of the spectral frequency distribution [F(slope)] in the lateral direction

	Condition	**Source comparison**	***f***	***p***
Within subjects factor	Eyes-open	1) Time*group	0.02	0.88
		2) Device*group	0.88	0.36
	Eyes-closed	1) Time*group	0.03	0.84
		2) Device*group	0.03	0.84
Between subjects factor	Eyes-open	Control - Experimental	1.06	0.31
	Eyes-closed	Control - Experimental	1.89	0.18

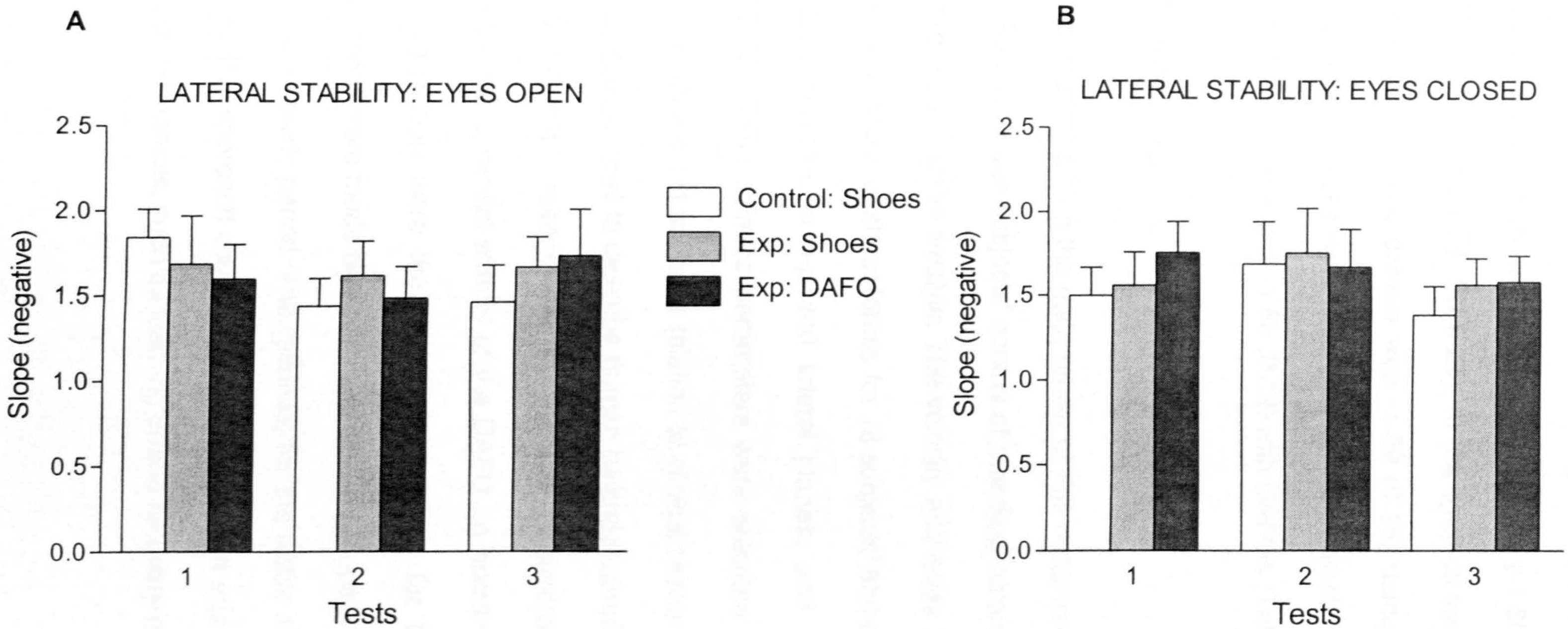


Figure 3.13 Slope of the spectral frequency distribution in the medial-lateral plane. Tests were carried out with subjects' eyes open (A) and eyes closed (B). Control subjects (n = 8) were tested wearing their own shoes. Experimental subjects (n = 10) were tested separately with their shoes and when wearing DAFOs. Measurements for all subjects were recorded on the 3 testing sessions as described in Methods. Data are mean and SD.

For the 5 subjects with a left side deficit, the mean F(slope) for the three sets of measurements made in the lateral plane with eyes-open was -1.51 (0.05) with shoes and -1.63 (0.14) using DAFOs. When using shoes, clearly greater negative values were evident for the subjects with a right side deficit (-1.80, SD 0.22) compared to when DAFOs were worn (-1.58, SD 0.23). In the eyes-closed condition, the F(slope) for the subjects with left side paresis was -1.59 (0.16) using shoes and -1.66 (0.12) using DAFOs; similar values were recorded for the subjects with paresis on the right side, -1.66 (0.16) with shoes and -1.68 (0.19) with DAFOs (Table 3.20).

3.2.2 Discussion

The first studies during the main phase of this research aimed to determine the effects of DAFOs on stroke subjects' control of standing balance, and therefore their potential to improve daily active lifestyle. The velocity and sway index of the CoP, and F(mean), F(sd) and F(slope) of shear forces for 18 subjects' standing balance were recorded with the force platform, in a-p and lateral planes, and in eyes-open and eyes-closed conditions. These balance parameters were selected for study because it is not yet known which is most useful in relation to clinical research on stroke patients. No single variable can be used to describe human balance completely. However, it was expected that a thorough assessment of multiple parameters would give more detailed information of potential effects of the DAFO on human balance and, possibly, identify which variable(s) were the most sensitive tool for this research application. Data comparisons were made between- and within- groups collected during three tests over a three-month study period. The rationale for the within experimental group comparisions was that this approach could potentially distinguish any direct effects of the DAFO from unrelated influences, such as learning or/and recovery effects.

Table 3.20 Summary of balance results:
LEFT and RIGHT hemiparesis - experimental subjects

Velocity of sway in a-p direction (mm/s) - mean (SD) *			
Eyes open	**Left**	**Right**	**Unpaired *t*-test (p<0.05)**
Shoes	18.66 (5.14)	21.22 (7.16)	ns
DAFO	19.46 (4.77)	22.45 (9.69)	ns
Eyes closed			
Shoes	22.29 (6.74)	28.20 (11.79)	ns
DAFO	22.07 (4.87)	28.37 (10.90)	ns
Velocity of sway in lat direction (mm/s) - mean (SD) *			
Eyes open	21.32 (3.84)	22.57 (4.34)	ns
Shoes	22.60 (4.25)	22.63 (5.74)	ns
DAFO			
Eyes closed	22.0 (4.02)	24.32 (6.32)	ns
Shoes	23.05 (4.30)	24.39 (6.23)	ns
DAFO			
Sway index in a-p direction - mean (SD) *			
Eyes open	**Left**	**Right**	ns
Shoes	5.85 (1.94)	5.04 (0.62)	ns
DAFO	5.40 (1.43)	5.55 (1.34)	
Eyes closed			ns
Shoes	6.53 (1.27)	6.64 (1.45)	ns
DAFO	6.38 (1.56)	7.38 (1.42)	
Sway index in lat direction - mean (SD) *			

Eyes open	**Left**	**Right**	
Shoes	4.44 (2.57)	3.84 (1.83)	ns
DAFO	4.10 (2.37)	3.84 (1.93)	ns
Eyes closed			
Shoes	4.82 (2.63)	5.47 (2.06)	ns
DAFO	4.20 (2.35)	5.31 (2.42)	ns

Mean spectral frequency in a-p direction – mean (SD) **			
Eyes open	**Left**	**Right**	
Shoes	1.55 (0.19)	1.63 (0.28)	ns
DAFO	1.57 (0.25)	1.61 (0.33)	ns
Eyes closed			
Shoes	1.61 (0.19)	1.71 (0.32)	ns
DAFO	1.66 (0.24)	1.79 (0.18)	ns

Mean spectral frequency in lat direction – mean (SD) **			
Eyes open	**Left**	**Right**	
Shoes	2.18 (0.12)	1.64 (0.21)	ns
DAFO	2.32 (0.19)	1.72 (0.34)	ns
Eyes closed			
Shoes	2.17 (0.17)	1.80 (0.32)	ns
DAFO	2.03 (0.23)	1.78 (0.15)	ns

Spectral frequency variability in a-p direction – mean (SD) *			
Eyes open	**Left**	**Right**	
Shoes	0.68 (0.07)	0.65 (0.09)	ns
DAFO	0.66 (0.11)	0.63 (0.16)	ns

Eyes closed			
Shoes	0.65 (0.09)	0.58 (0.1)	ns
DAFO	0.63 (0.07)	0.60 (0.15)	ns
Spectral frequency variability in lat direction – mean (SD) *			
Eyes open	**Left**	**Right**	
Shoes	1.23 (0.26)	0.86 (0.13)	ns
DAFO	1.33 (0.33)	0.93 (0.27)	ns
Eyes closed			
Shoes	1.15 (0.31)	0.88 (0.27)	ns
DAFO	1.03 (0.28)	0.84 (0.18)	ns
F(slope) in a-p direction – mean (SD) * **			
Eyes open	**Left**	**Right**	
Shoes	-1.64 (0.12)	-1.72 (0.15)	ns
DAFO	-1.67 (0.15)	-1.66 (0.15)	ns
Eyes closed			
Shoes	-1.63 (0.08)	-1.75 (0.11)	ns
DAFO	-1.63 (0.17)	-1.75 (0.24)	ns
F(slope) in lat direction – mean (SD) * **			
Eyes open	**Left**	**Right**	
Shoes	-1.51 (0.05)	-1.80 (0.22)	ns
DAFO	-1.63 (0.14)	-1.58 (0.23)	ns
Eyes closed			
Shoes	-1.59 (0.16)	-1.66 (0.16)	ns
DAFO	-1.66 (0.12)	-1.68 (0.19)	ns

* = lower value indicates better balance control

** = higher value indicates better balance control

*** = less negative value indicates better balance control

Collectively, the present studies consistently found no statistically significant differences between the balance parameters studied, when subjects used a DAFO or when wearing shoes. This situation was apparent when the statistical comparisons were performed on a between- and within-group basis. It was hypothesised that DAFOs improve motor behaviour after stroke involving the acquisition of standing balance (Hypothesis I). It may be argued, therefore, that this hypothesis should be rejected, i.e. the distributions of values in the DAFO and shoe users groups are probably the same, and it may be concluded that there is no evidence for effects of the DAFO on these subjects' balance. However, this simplistic conclusion may be unjustified. The statistical power of the present work may have been insufficient to detect small and potentially important changes in the subjects' balance characteristics. Furthermore, with the numbers available, it cannot be assumed that these subjects formed a true representation of the entire stroke population. It is emphasised that stroke encompasses high heterogeneity in terms of pathology and disability. Consequently, careful consideration was given to the best way to proceed with the data analysis. As the data most often approximated a normal distribution, it was decided that parametric analyses of grouped data were most appropriate. Whilst accepting the limits of the analyses, this approach did provide anecdotal evidence suggesting that DAFOs might influence some aspects of stroke patients' balance, and these findings merit consideration.

The findings of the studies may be summarised as follows. Between group (control and experimental) comparisons demonstrated that when the experimental subjects used DAFOs, consistently lower values in lateral velocity of CoP were obtained in both visual conditions (section 3.2.1.3). In addition, within group comparisons (using shoes or DAFOs) indicated that the CoP sway indices parameters were, potentially, sensitive to DAFO intervention. This was evident in Test I and Test III, and only in the eyes- closed condition (section 3.2.1.4). Further balance analyses demonstrated that the F(mean) parameters of shear forces were better using DAFOs in the experimental group

compared to the control group who used shoes alone. However, these positive effects were only indicated in the a-p direction when the subjects' eyes were closed (section 3.2.1.5). Nonetheless, the variability of shear forces, F(sd), demonstrated steadier balance control in both directions, and under both visual conditions, for the experimental group than for the control group (section 3.2.1.6). Contradictory findings were obtained to suggest that the control group provided nearer normal CoP sway index parameter values compared to the experimental group with DAFOs (section 3.2.1.3). The following discussion considers the results of these studies without further qualification; statistical and other forms of limitations that may be relevant to the explanations and proposals offered here are addressed in the General Discussion.

The first balance variables assessed were CoP parameters. The velocity of CoP sway is defined as a control for static standing (Era *et al.*, 1996; Nougier *et al.*, 1997; Pushpangadan *et al.*, 1999). In the present studies, the CoP velocity indicated overall higher (statistically significant) values (reduction of postural control) in the stroke subjects groups compared to the healthy subject group (section 3.2.1.3). Earlier work on stroke patients' standing balance performed using similar tests supports this finding (Shumway-Cook *et al.*, 1988; Sackley, 1991; Portfors-Yeomans and Riach, 1995; Goldie *et al.*, 1996). The increase in sway is believed to reflect deterioration of stroke patients' balance control mechanisms (including eyesight, sensation and muscle reflexes) when standing, due to inefficient neuro-transmission, which is exacerbated by the weakened muscles (Kirker *et al.*, 2000).

The static standing balance tests (section 2.4) conducted with the subjects' feet in a parallel (feet apart) position revealed a larger lateral velocity of sway than was evident in the a-p plane for both control and experimental groups. Lateral stability is predominantly controlled by the hip-strategy, which involves the hip abductor and adductor muscles (Maki *et al.*, 1992). This finding is supported by earlier published studies (Williams *et al.*, 1997; Blaszczyk *et al.*, 2000; Walker *et al.*, 2000), which demonstrated increased lateral

sway with stroke and in those studies where healthy elderly subjects were compared to young subjects. For healthy subjects, increased lateral sway is explained by the difficulties in generating sufficient ankle-torque, and therefore the control of lateral stability in standing maybe more prominent (Woollacott *et al.*, 1986; Winter, 1995; Williams *et al.*, 1997). Studies of stroke subjects have also demonstrated that if patients cannot recruit the hemiparetic muscles quickly enough to maintain their balance, they must rely on the muscles of the unaffected leg, and lateral stability deteriorates (Kirker *et al.*, 2000). Clearly, the present findings are in accord with these explanations.

The lateral velocity of sway consistently provided lower values (indicative of better balance) for the DAFOs users (the experimental group) than the shoes users (the control group). This might be explained by improved stability on the affected leg, and therefore decreased lateral sway during static standing. This possible DAFO-mediated action on lateral velocity of sway was evident under both visual conditions. A positive effect on reduced lateral velocity of sway due to a DAFO could be due to the mechanical support afforded by the splint around the ankle, which enabled the subject to place the foot on the floor more confidently. Thus, although the construction of the splint is low, its rigidity still provides considerable support for the ankle over the malleoulus, whilst maintaining effective flexion-extension movements of the ankle (section 1.4.2). This may be evident as effects on the lateral velocity of sway. Physiologically, it is possible that mechanical support provided by the DAFO, which leads to a decrease in lateral sway, improves the recruitment of the hip muscles activity on the affected leg, particularly via expanding ankle plantarflexion activation. Thus, it was theorised that lateral sway of balance is controlled via hip abductor-adductors muscle activity, which is closely related to ankle plantarflexion activity (Diener *et al.*, 1993; Gilles *et al.*, 1999; Kirker *et al.*, 2000). However, it is notable that in the present investigations, within-test analysis (DAFO vs shoes only) indicated no clear data

differences. It is unknown whether unrelated factors (e.g. physiological or technical) or an influence of possible learning or recovery effects explain this discrepancy.

The sway index describes the variability of the position of the CoP as a function of time, and indicates the variability of the location of the point of application of the resultant ground reaction force relative to the feet, and is commonly used as a measure of stability (Winter, 1991b; Saunders *et al.*, 2002). In the present studies, the healthy subjects' CoP sway index was found to be substantially lower (statistically significant) than for the stroke (control and experimental) subjects, which is in accord with earlier work (Shumway-Cook *et al.*, 1988; Goldie *et al.*, 1996; Kirker *et al.*, 2000). There are several earlier reports of studies on the elderly where increased amplitude of CoP (Wing *et al.*, 1993; Bhakta and Bamford, 2002) and higher frequency content of the CoP signal have been associated with unsteady balance (Kirker *et al.*, 2000; Pollack *et al.*, 2002).

Comparisons of the control and experimental groups CoP sway indices values indicated no statistically significant differences. It is notable that in these experiments, the variability (SD) was large. Despite this, the control group's mean values were always lower than in the experimental group. Lower sway index suggests steadier balance control for the control subjects than for the experimental subjects in both a-p and lateral directions (section 3.2.1.4). Thus, the visual condition did not alter the sway index data. Although at present speculative, it seems possible that this potentially lower sway index and the CoP velocity parameter in the a-p plane data presented earlier (for the control group) are in accord. Both parameters represent a displacement measure, which is a function of the vertical ground reaction vector that requires good muscle control of the lower limbs when controlling movements of centre of gravity. The results of the manual muscle test, done at the beginning of the study, highlight some differences between the groups. Thus, the control group provided somewhat higher values and therefore these subjects could be perhaps physically stronger than in the experimental group (Appendix III). In addition, ADL assessments indicated differences between groups in relation to

independence for housework and other physical activities within the home environment. Although these differences did not achieve statistical significance, the data were consistent with numerical poorer values for the experimental group. Furthermore, the use of the walking aids (by 2 subjects from 8 in the control and 8 subjects from 10 in the experimental group) may point to some balance problems during the daily life in the experimental group.

The CoP sway index data were also compared within the experimental group, when subjects used DAFO or shoes, in an attempt to delineate any effects in individual tests. This analysis revealed some interesting observations. The sway-index yielded lower values for lateral sway using DAFOs than for using shoes; particularly in test I and III. In this plane, the sway-index data using DAFOs was found to be almost 20 % lower than with shoes during the baseline test, in this experimental group. The magnitude of this difference decreased slightly by test III, but was still substantially lower compared with using shoes.

Recently, the theory that increases in the amplitude of the CoP under 'safe' laboratory conditions is representative of balance loss has been questioned (Nadeau *et al.*, 1999b). Such doubts have been reinforced by the findings of clinical studies, which have reported decreases in CoP amplitude (Shumway-Cook *et al.*, 1988; Stroke Unit Trialists' Collaboration, 2001). Balance studies of the elderly 'at risk of falling' have focused on this issue; it has been speculated that the traditional measures of CoP may be inappropriate or inadequate for describing more complex aspects of the stability of postural control systems (McClenaghan *et al.*, 1995; Nadeau *et al.*, 1999b; Kejonen and Kauranen, 2002). Williams *et al.* (1999b) reported that calculation of the shear (horizontal) forces using spectral analysis methods is a useful tool for identifying biomarkers associated with potential loss of functional balance capacity.

The horizontal (shear) forces were used because they describe the accelerations of the centre of mass. These accelerations represent the vibrations of the centre of the body

or the spectral characteristic of the postural control. It has been suggested that this property provides a more sensitive means of identifying impaired balance in complex neurophysiological systems compared to the measurement of the resultant ground reaction forces under both feet (McClenaghan *et al.*, 1995; Nadeau *et al.*, 1999b; Kejonen and Kauranen, 2002). In the present study, comparing shear forces (Fmean, Fsd and Fslope) of static standing between and within the experimental groups using DAFOs and shoes demonstrated that there is no evidence that DAFOs are more effective than shoes in promoting standing balance measured by these parameters. However, it was interesting to note that the measurements of spectral frequency demonstrated that, in the a-p direction, the mean spectral frequency (Fmean) was marginally higher, suggesting better balance control for the experimental than the control group. This was evident in the eyes-closed condition but not in the eyes open condition (section 3.2.1.5). The present finding of altered F(mean) with subjects' eyes-closed could support the possibilities that DAFOs may enhance the processing efficacy of other sensory (proprioceptive) information, which contributes to foot and ankle stability during balance control in the absence of visual cues. Comparable results were reported by Williams *et al.* (1999b), who utilised these parameters as a clinical tool to identify balance problems in elderly individuals. A higher F(mean) value was shown to be correlated with better balance function in healthy young and elderly subjects (McClenaghan *et al.*, 1995; Nadeau *et al.*, 1999b). These authors also reported that healthy elderly subjects displaying low F(mean) values have greater risk factor indices in relation to falls. In addition, Maki *et al.* (1992) described overall low mean frequency characteristics of subjects who had experienced falls; elderly individuals with poor balance were characterised by greater concentration of power at low frequencies. It was assumed that for control subjects, small postural control drifts were either difficult to identify, or corrected for by the postural control system and that, alternatively, both systems might respond to larger postural drift with low frequency corrections. In the context of the present studies, it is possible that the experimental stroke subjects with

DAFOs effects approached the limits of stability before postural drift perception and/or when acted upon, particularly on the a-p direction and when the eyes were closed.

Interestingly, the variability (Fsd) of spectral frequency values recorded were consistently lower, and therefore could indicate steadier balance for the experimental group than for the control group. The effect was seen in both a-p and lateral directions of sway and under both visual conditions. Earlier studies of healthy elderly subjects demonstrated that shear forces particular in the lateral plane were shown to be a more sensitive variable than a-p sway (Williams *et al.*, 1997). It is believed that F(sd) is more sensitive for distinguishing balance changes because of its propensity to reflect adaptation to environmental conditions, which therefore provides low variability values (Williams *et al.*, 1997) as observed here. Whether DAFOs are involved in this action is debatable. However, it is emphasised that this variable in itself cannot be assumed to fully describe an individual's balance ability. As already indicated, human balance is complex, incorporating multiple physiological and biomechanical systems and constraints. This variable is simply one aspect of balance control that can be isolated and measured.

Furthermore, the negative slope (Fslope) of lesser magnitude is also suggestive of attenuated loss of high frequency variability (steadier balance) (McClenaghan *et al.*, 1995). However, in the present studies, the data did not suggest any clear differences between DAFO or shoe use. The within-group comparisons with F(mean) and F(sd) of shear force data (section 3.2.1.5) also failed to provide consistent differences between shoes or DAFOs.

Currently, the literature still contains no detailed descriptions of the effects of DAFOs on stroke patients' balance. Most of the earlier reports consisted of single-case designs, used devices other than a DAFO, or/and examined patients over a different time scale than used here. Earlier work has focused mostly on the potential for DAFOs to influence

stroke patients' gait (section 1.4.2.2). Consequently, only indirect comparisons of the present findings to earlier work are possible.

Here, no statistically significant effects of DAFOs on stroke patients' balance parameters compared to shoes were identified. These findings are consistent with those of Woolley and colleagues (1996), who studied five stroke and head injured subjects' balance and found no statistically significant differences between DAFOs, AFOs and barefoot. A similar lack of orthosis effect was reported by Wong *et al.* (1992), who tested an anterior AFO and conventional AFO on six stroke subjects' balance. Contradictory findings were reported by Chen *et al.* (1999), who examined the effects of an anterior AFO on 24 stroke subjects' static and dynamic standing balance, and concluded that the device had no effect on a-p balance (postural sway and symmetry, and weight shifting). However, a significant and positive effect of the AFO on lateral weight shifting and bearing through the affected leg was noted. Thus, these findings are also in accord with the present investigations, in that here some parameters suggested a greater effect of the DAFO than shoes on lateral sway, and no consistent differences in a-p sway over the 3 month testing trial period. Determination of whether DAFOs can influence stroke patients' balance and whether lateral sway could be a more sensitive measure of stroke patients' balance in relation to use the of this device will clearly require further study

3.3 Main phase - Gait

This section presents the results of gait tests performed during the main study phase of the research. These investigations used protocols that were modified in accordance with the findings of the preliminary work presented earlier and in Appendix I. In the gait tests, the effects of the orthoses were evaluated using several gait variables. As for the balance studies, data comparisons were made here between the control group (shoes users) and the experimental group (DAFO users). The experimental group subjects were also assessed under two different conditions: using either the DAFO or shoes-

only; as before, the rationale for this was identification of direct effects of the DAFO separate from unrelated influences, such as natural recovery.

The results are divided into four sub-sections. Firstly, the demographic characteristics of the different subject groups are presented, together with group comparisons. This is followed by the findings from studies of subjects' performance as indicated by the spatio-temporal variables (velocity, stride length, step length, cadence, and single stance phase) from the affected and unaffected legs during two full gait cycles. Thirdly, the findings of studies on the effects of DAFOs on kinematic gait parameters, analysed in terms of the subjects' sides that were affected and unaffected by stroke, are presented. The parameters studied were minimum angular displacement and minimum/maximum velocity of the foot, shank, and thigh segments during two strides (i.e. the gait cycle). This is followed by the results of comparisons of the relationship between gait and balance. The findings of the studies on subjects' gait are then discussed in relation to the efficacy of DAFOs for stroke patients' ambulation. Finally, the results of the experimental subjects' opinions concerning the use of DAFO are presented and discussed. For all statistical comparisons, the *p* value for significance is 0.05.

3.3.1 Results

3.3.1.1 Subject characteristics

Thirteen of the 22 subjects recruited completed the main phase of the gait studies (3 control and 10 experimental). The reasons for not completing the trial were further personal reasons (4). Further, the data sets collected for five subjects were archived incorrectly due to unforeseen technical (software) problems and were discarded. The demographic characteristics and distribution details for the subjects who completed the trial are shown in Table 3.21. The values for subjects' age, weight and height followed a normal distribution ($p > 0.01$, Dallal and Wilkinson approximation to Lilliefors' method)

and the mean values for each of these factors were not significantly different between groups ($p > 0.05$, unpaired *t*-test). In the control group, all of the subjects walked without a 'walking aid' (one used a wheelchair for longer distances outside). In the experimental group, two of the subjects walked without a walking aid, seven subjects used a walking stick and one needed a walking frame inside. When experimental subjects walked outside, seven subjects used a wheelchair, one subject needed a walking frame and two subjects required no aids.

All of the experimental subjects used a DAFO for the entire duration of the studies. The design of the testing sessions required that subjects in the experimental group used casual shoes followed by DAFOs. During the second and third tests, one of the experimental subjects (E9) had difficulties in walking safely without a DAFO. Consequently, for this subject, only gait data collected when using the splint was recorded.

Table 3.21 Demographic details of subjects who completed the gait tests

Group	Sex	Age in years	Side of paresis	TS in months	Weight in kg	Height in cm	Walking aids
CNTRL	3 M	58.0 (52-68)	2 left 1 right	9.3 (6-15)	89.7 (86.6-92.4)	171.5 (170-173)	No aids (2) Stick (1)
EXP	3 F 7 M	68.9 (54-87)	5 left 5 right	8.2 (4-15)	74.3 (61.2-92.4)	166.6 (153-174)	No aids (2) Stick (7) Frame (1)

Mean and (range), TS = time since stroke

Healthy subjects

Healthy elderly subjects were recruited in order to construct a comparative database. Each of these subjects was tested during a single trial. The demographic characteristics of the healthy subjects that were tested are shown in Table 3.12.

3.3.1.2 Functional ability in everyday life

Due to the differences between the sample sizes of the subject groups used for these investigations and the balance assessments (section 3.2.1.2), the data for subjects' functional abilities were re-evaluated. Mann-Whitney U-tests indicated that there were differences in score values with borderline statistical significance between the control and experimental groups using the Nottingham Extended ADL (p = 0.077), and the functional RMA (p = 0.049) scales. The leg and trunk RMA values of the control group were significantly higher than for the experimental group (p = 0.014). The results of these analyses are summarised in Table 3.22.

Table 3.22 Subjects' functional assessment scores

Scale	***CNTL group*** (n = 3)	***EXP group*** (n = 10)
Nottingham ADL score	49 (33 - 61)	31 (11 - 43)
Rivermead Motor - Functional test score	11 (10 -11)	8 (3 - 11)
Rivermead Motor - Leg and Trunk score	5 (5 - 6)	3 (1 - 5)*

Data are mean and (range) of the 3 tests carried out over a 12 weeks period as described in Methods. * Significantly different from control group, $p < 0.05$.

3.3.1.3 Spatio-temporal factors of gait

Velocity

Gait velocity is believed to represent one of the most important variables to assess in studies of stroke subjects, as it reflects both functional and physiological changes in affected individuals (Olney and Richards, 1996; Baer and Smith, 2001). Increased gait velocity is indicative of improved performance (Wooley, 2001). Subjects' gait velocity (m/s) was determined by measuring the rate of travel indicated by the time required to cover a predefined distance (section 2.6.5). In the healthy subject group (n = 4), the mean and (SD) values for gait velocity recorded simultaneously for both legs were 1.11 (0.15) m/s for the right leg and 1.14 (0.05) m/s for the left leg. These values are consistent with those reported by Judge *et al.* (1996) and Witte and Carlsson (1997) for elderly walkers. The present data also suggest a small difference between left and right leg gait velocities for healthy subjects. It is notable, however, that the magnitude of this difference was less that 0.5 SD. Nonetheless, this difference is consistent with earlier reports, where gait velocity data for both legs were (Murray *et al.*, 1975; Öberg *et al.*, 1993).

The gait velocities calculated for the control group subjects (n = 3) were 0.80 (0.15) m/s and 0.84 (0.17) m/s, for the affected and unaffected sides, respectively. In contrast, the values recorded for the experimental group subjects (n = 10) on the affected side were 0.35 (0.18) m/s using shoes only, and 0.37 (0.22) m/s with DAFOs. On the unaffected side, the velocity recorded using shoes was 0.37 (0.19) m/s. When a DAFO was used on the unaffected leg the value was 0.36 (0.2) m/s. Ordinary ANOVA detected a significant ($p < 0.01$) difference between gait velocities calculated for the healthy, control and experimental subjects. Bonferroni's multiple comparison post-test indicated that the relative order of gait velocity was healthy subjects > control subjects > experimental subjects.

Brain damage due to stroke primarily results in contralateral affects on gait. Thus, a stroke affecting the left side of the brain leads to right sided paresis and vice versa. Nonetheless, when assessing gait performance of stroke subjects, it is clearly useful to assess both sides separately, because there may be inherent differences between variables (Titianova and Tarkka, 1995). Furthermore, although usually less apparent, a lesion of one side of the brain does not preclude motor deficits on the same side of the body. In the present studies, the unaffected side variability was found to be slightly higher in the control group compared to the experimental group. However, although the SD on the affected side using shoes was high, and variability using DAFOs was low, a clear pattern was not evident. The mean gait velocities of the stroke subjects (control and experimental groups) were significantly slower ($p < 0.01$) than for the healthy subjects (the mean difference was 0.40 m/s for the control subjects, 0.87 m/s for the experimental subjects using shoes, and 0.85 m/s for the experimental using a DAFO). The corresponding values of the control ($n = 3$) and experimental groups ($n = 10$) were also significantly different ($p < 0.01$), with a slower mean gait velocity evident for the experimental group (the mean difference was 0.47 m/s for the experimental group using shoes, and 0.44 m/s for the experimental group using a DAFO, see Figure 3.14).

In order to assess the potential for an influence of lateralization, the data obtained from these studies were separated according to side of paresis. For the experimental subjects, the mean gait velocity values of the right side hemiparesis subjects were not significantly different compared to those with a left side deficit ($p > 0.05$). Similar results were obtained with or without a splint.

Further examination of these data revealed that the experimental subjects could be characterised as either relatively 'slow' or 'fast' walkers. Thus, it can be seen that despite some overlap, in general, subjects 1 - 5 were slower walkers than subjects 6 - 10 (Figure 3.15). Sub-division of data leads to an inherent reduction of power for

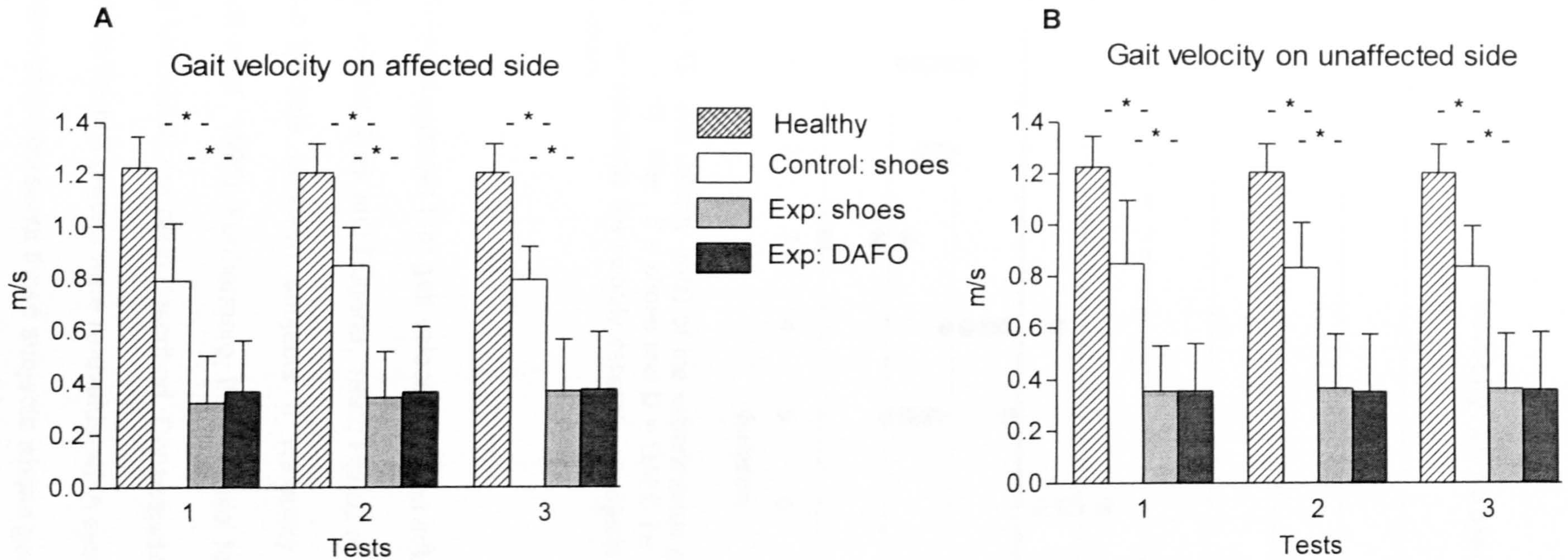


Figure 3.14 Control (n = 3) and experimental (n = 10) subjects' gait velocities (m/s). The experimental subjects' gait velocities are shown when using shoes and DAFOs for the side affected and unaffected by stroke. For comparative purposes, data collected using healthy (n = 4) subjects (average of both legs) are also given. Values for all subjects were calculated from two strides in three separate tests as described in Methods. Values are mean and SD. * Significant difference between the control group and experimental groups and the healthy comparative group, $p < 0.01$, unpaired t-test.

statistical analyses, but may still permit identification of potentially important differences (Anthony, 1999).

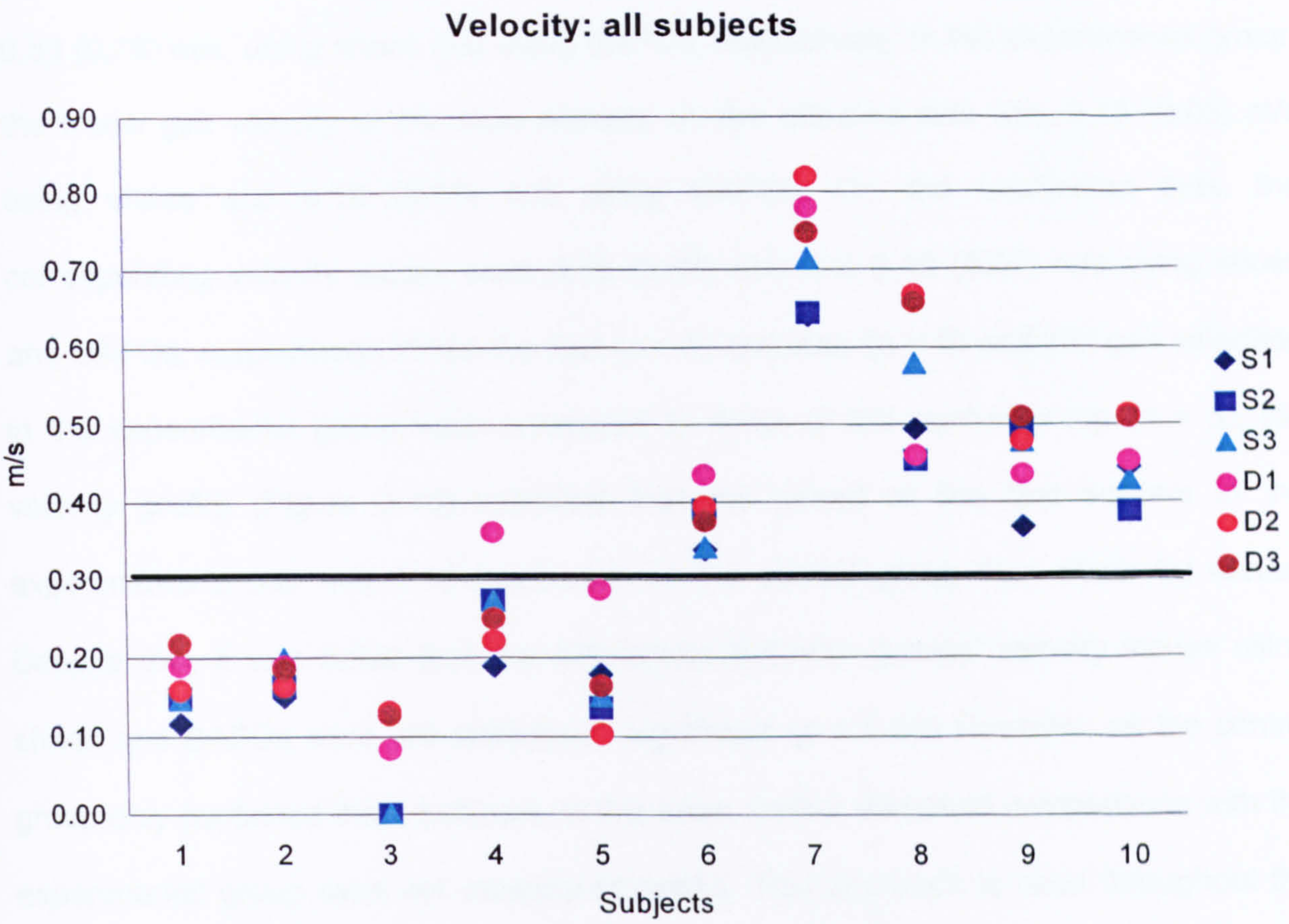
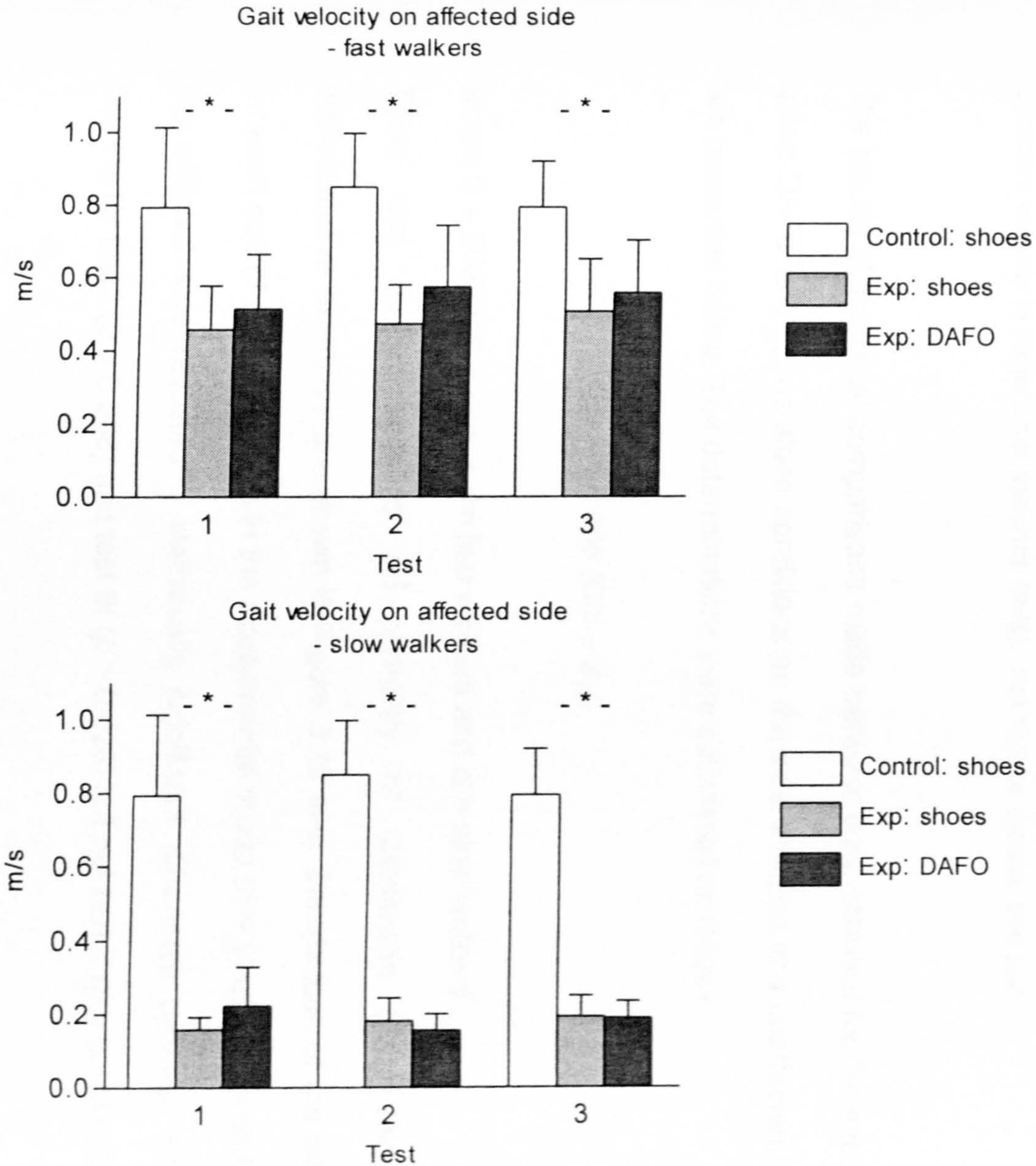


Figure 3.15 Gait velocity (m/s) of the experimental group. Data are shown for individual subjects (1 - 10). Key: S = shoes and D = DAFO for the corresponding tests (1 – 3). The bolded line represents the velocity separating subjects into slow (< 0.3 m/s) or fast (≥ 0.3 m/s) walkers.

It has been suggested that gait velocity may be influenced by spatio-temporal variables (Winter, 1991b; Craik and Dutterer, 1995; Prince *et al.*, 1997) and values are likely to be less comparable between subjects if variability between measurements is large (Turnbull *et al.*, 1995). Furthermore, the potential for selectivity of DAFO effects due to walking speed has not been described. Consequently, the data for stroke subjects' gait in the experimental groups were re-evaluated. A system was used in which slow walkers were deemed to represent those subjects whose gait velocity was < 0.3 m/s; fast walker status was assigned to subjects whose gait velocity was ≥ 0.3 m/s (Figure 3.15).

The control group exhibited gait velocities in the range 0.6 - 1.1 m/s and therefore could clearly be best described as fast walkers. In the experimental group, on the affected side, the fast walkers' gait velocity was 0.50 (0.13) m/s using shoes and 0.55 (0.16) m/s using DAFOs. On the unaffected side, the values recorded were 0.52 (0.11) m/s and 0.53 (0.18) m/s, using shoes and using DAFOs, respectively. In the experimental group, the mean gait velocity of the slow walkers on the affected side was 0.18 (0.05) m/s using shoes and 0.19 (0.07) m/s using DAFOs. On the unaffected side, the corresponding velocity values were 0.18 (0.06) m/s and 0.19 (0.07) m/s using shoes and DAFOs, respectively. When the fast (n = 5) and slow (n = 5) walkers' gait velocities in the experimental group were compared to those of the control group (n = 3), the velocity profile (Figure 3.16) indicated that the speed of the fast walkers in the experimental group was 0.18 m/s nearer to the control group than observed earlier. Despite this, it was noted that the differences between groups' velocity values using shoes and DAFOs were still statistically significant ($p < 0.05$) However, as the control group only contained three subjects, in this case, further statistical comparisons with the experimental group were not considered useful. This approach is used throughout the remainder of this thesis unless stated otherwise.

In order to examine the potential effects of DAFOs in more detail, within-group (experimental) data analyses were undertaken. The differences between the DAFO and shoe-alone conditions over three tests within the experimental group are shown in Figure 3.17. Data are given for the three tests and as the individual difference of DAFO (D) minus shoe (S) velocity values for each subject, denoted as D1-S1, D2-S2 and D3-S3. Here, values < 0.0 represent results where velocity was increased in the shoes-alone condition, and values > 0.0 values indicate an increased in gait velocity with the DAFO.



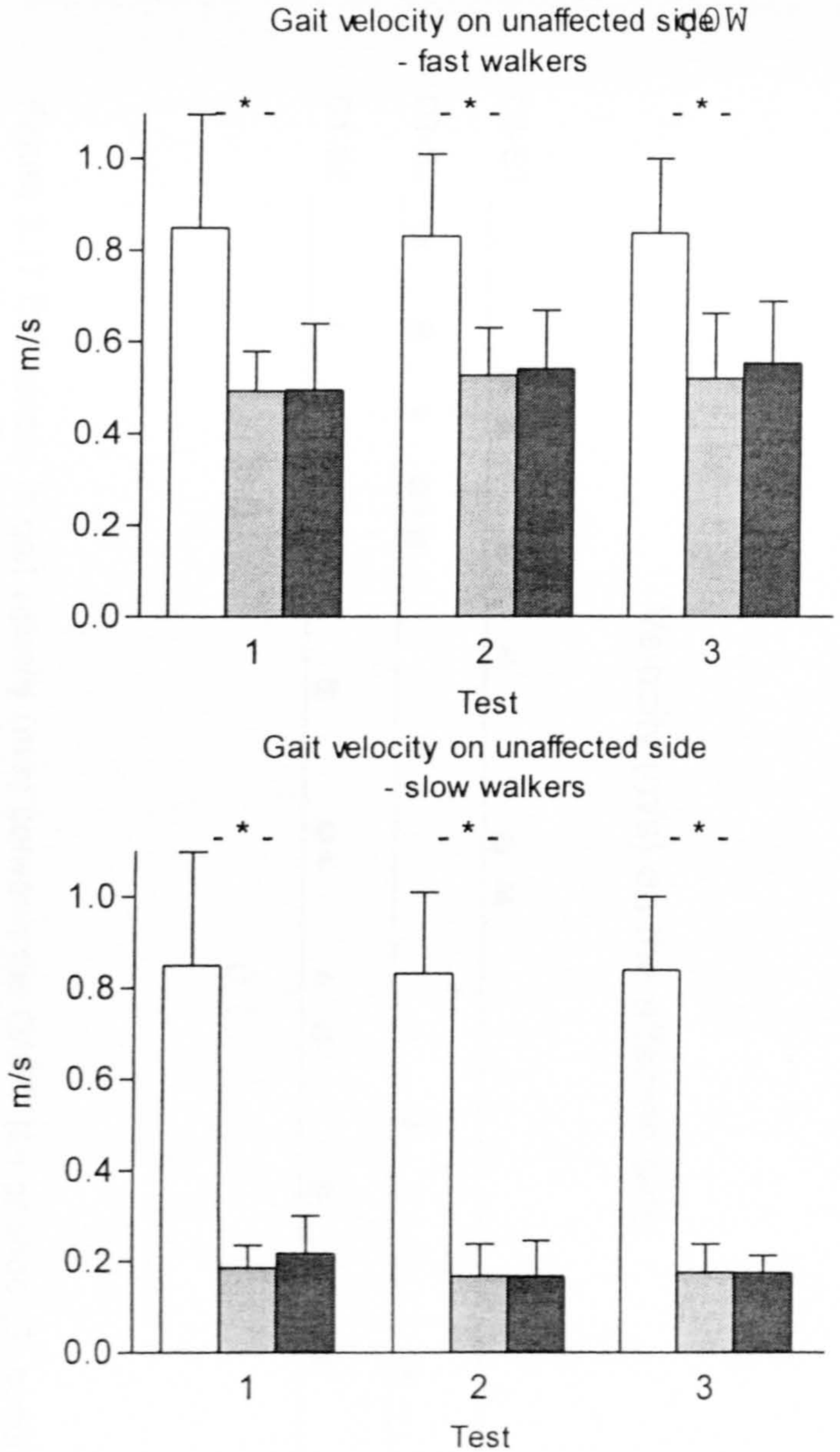


Figure 3.16 Control (n = 3) and experimental (fast walkers, n = 5; slow walkers, n = 5) subjects' velocities (m/s) for the side affected and unaffected by stroke. Experimental subjects' values are given when using shoes and DAFOs. Values are the mean and SD of three separate tests as described in Methods. * Significant difference between the control group and experimental fast and slow walkers groups, $p < 0.01$, unpaired t-test.

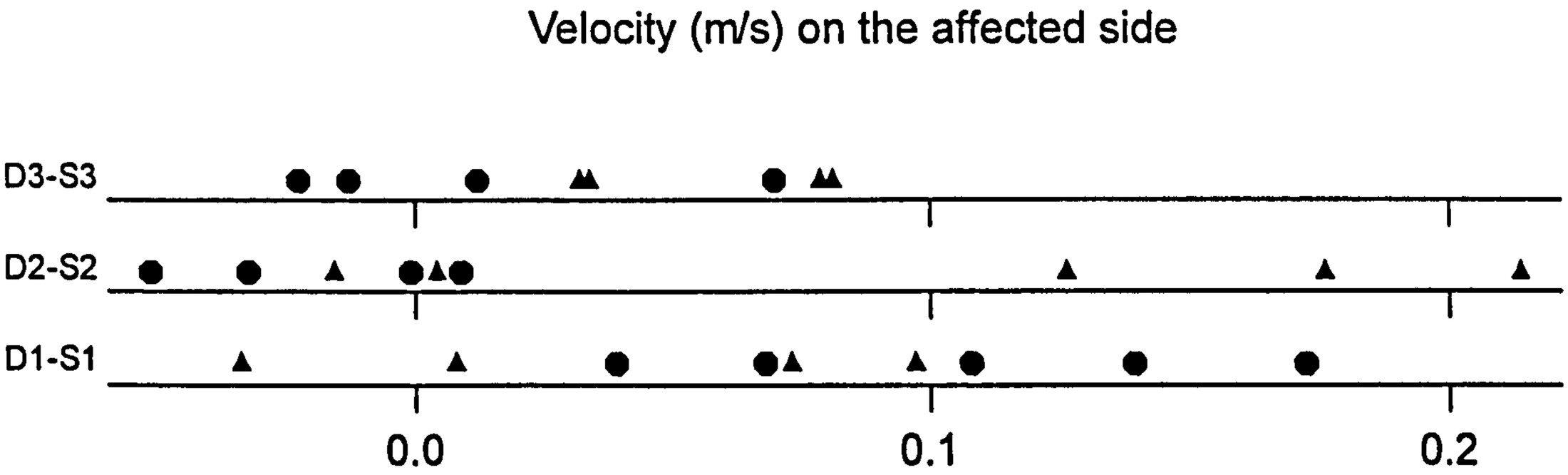


Figure 3.17 Differences in gait velocity (m/s) between the DAFO (D) or shoe (S) condition for the experimental group. Each symbol represents an individual subject; triangles indicate fast walkers and circles indicate slow walkers. 1-3 denotes test number. The values shown on the x-axis represent velocity in meters per seconds (m/s). For further details, see text.

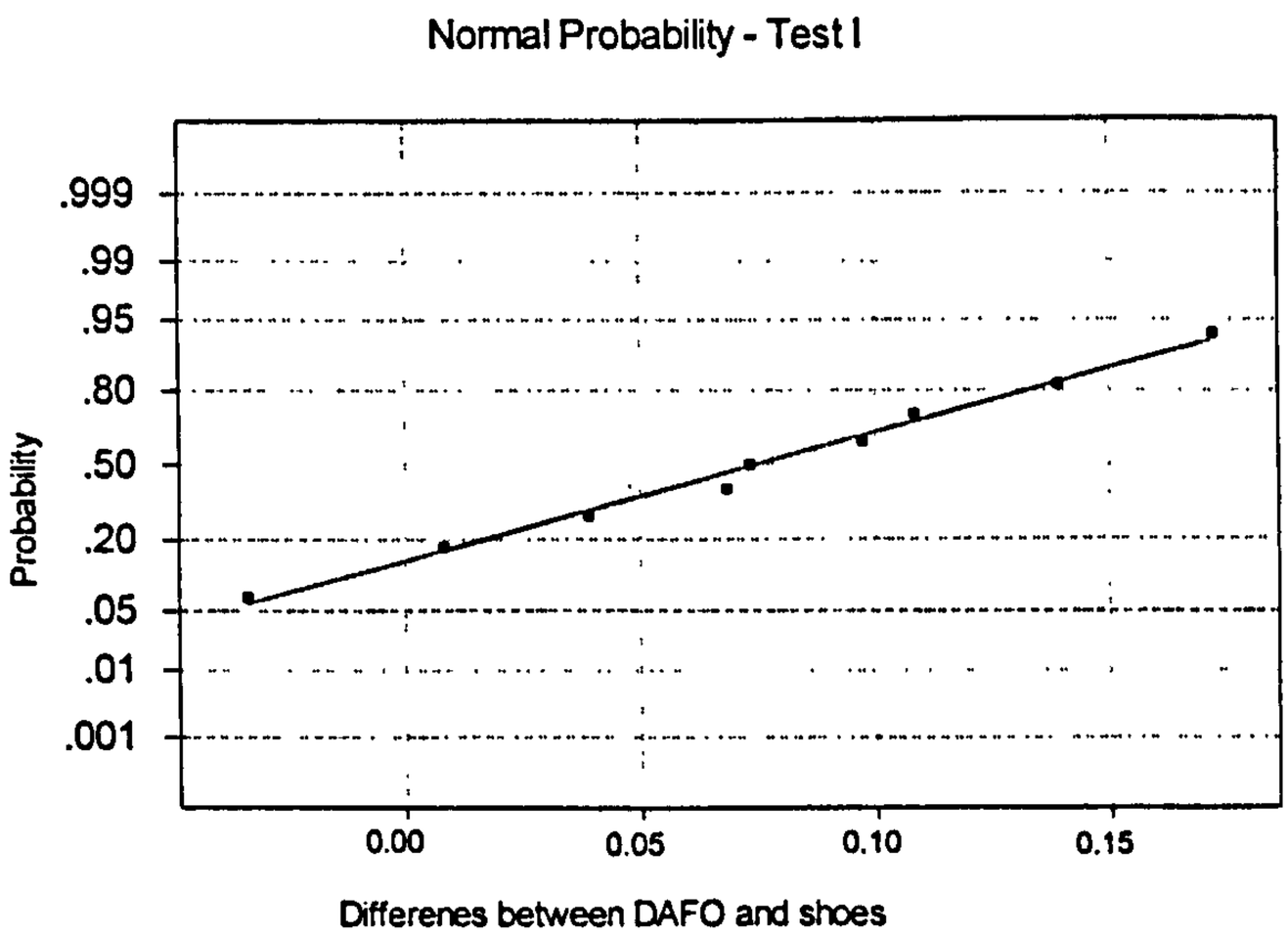
The results of statistical comparisons made between data obtained for the experimental group DAFO and shoes-alone conditions on the side affected and unaffected by stroke are presented below. The determinations were calculated as follows:

$$(D_f - S_f) \text{ and } (D_{sl} - S_{sl})$$

where D = DAFO, S = shoes, *f* = fast walkers and *sl* = slow walkers.

There was no evidence of non-normality of distribution (Ryan-Joiner test); representative examples are shown in Figure 3.18 a–c. Comparison of the differences for each pair of measurements in the experimental group ($n = 9$) using paired *t*-tests for the affected side revealed a statistically significant difference between shoes and DAFOs for test I ($p = 0.008$) and test III ($p = 0.028$) but not test II ($p = 0.184$). The

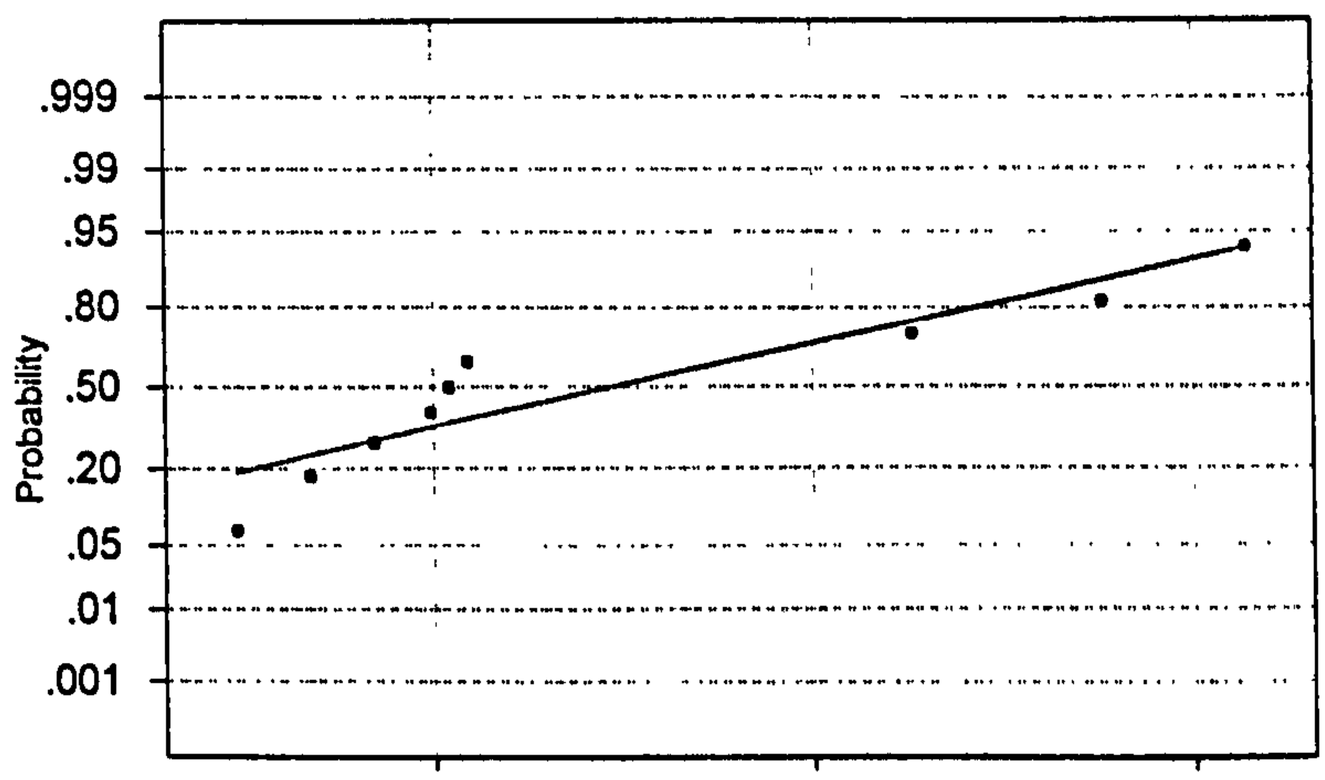
a



Average: 0.0744444
StDev: 0.0640256
N: 9

W-test for Normality
R: 0.9957
P-Value (approx): > 0.1000

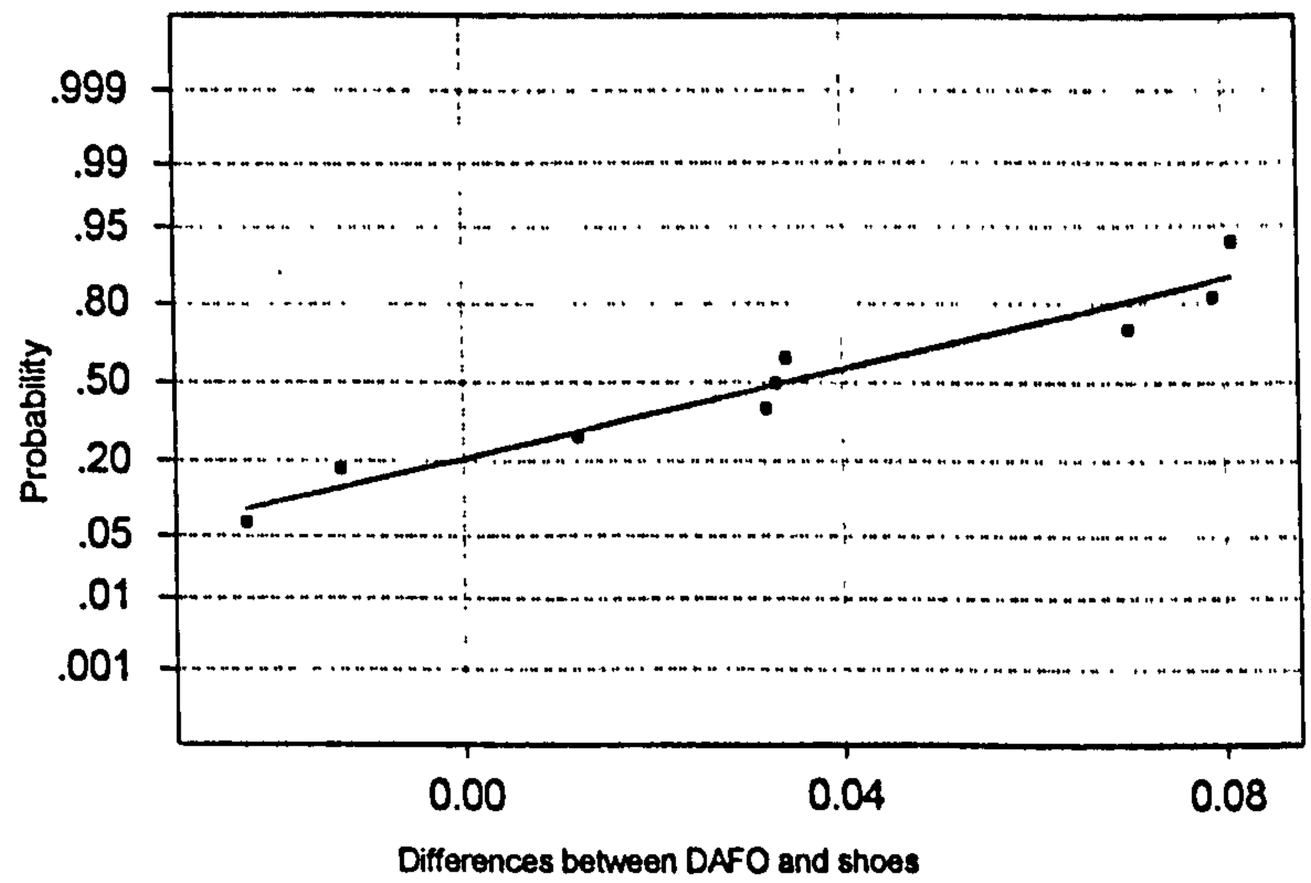
b



Average: 0.0474444
StDev: 0.0978112
N: 9

W-test for Normality
R: 0.9233
P-Value (approx): 0.0813

c



Average: 0.0338889
StDev: 0.0378763
N: 9

W-test for Normality
R: 0.9692
P-Value (approx): > 0.1000

Figure 3.18 Normality calculations for the experimental (*n* = 9) subjects' velocity values over the three tests (Ryan-Joiner test). X-axis presents individual differences in gait velocity (m/s) between DAFO and shoe condition.

velocity increased by 0.074 m/s using a DAFO compared using shoes in test I and by 0.034 m/s in test III (Table 3.23). However, the CI for these data indicated considerable variability, which may be due to the limited number of subjects, or the highly consistent velocity values recorded in test III. There was no statistically significant difference evident between the values recorded for the DAFO and shoes condition on the subjects' side unaffected by stroke.

Table 3.23 Summary of statistical tests (paired *t*-tests) on velocity determinations for the experimental group using shoes and DAFO (affected side).

Variable	**Mean**	**95.0% CI**	***p***
Test I	0.074	(0.025, 0.124)	0.008**
Test II	0.047	(-0.028, 0.123)	0.184
Test III	0.034	(0.005, 0.063)	0.028*

* = $p < 0.05$, ** = $p < 0.01$.

Further analyses based on the fast ($n = 5$) and slow ($n = 4$) walker classification revealed a significant increases of 0.052 m/s in gait velocity using DAFOs compared to using shoes for test III ($p < 0.01$, paired *t*-test) for fast walkers, and 0.098 m/s using the DAFO for test I ($p < 0.05$) for slow walkers, on the side affected by stroke (Table 3.24). Differences between DAFO and shoe velocity values on the unaffected side were not statistically different.

Table 3.24 Summary of statistical tests (paired *t*-test) on velocity determinations for the experimental group according to fast and slow walkers' status on the affected side.

Group/ test	Mean	95.0% CI	*p*
Fast/ test I	0.055	(-0.030, 0.141)	0.147
Fast/ test II	0.101	(-0.026, 0.228)	0.093
Fast/ test III	0.052	(0.011, 0.084)	0.011*
Slow/ test I	0.098	(0.007, 0.188)	0.041*
Slow/ test II	-0.019	(-0.064, 0.026)	0.266
Slow/ test III	0.012	(-0.055, 0.078)	0.620

* = $p < 0.05$.

Stride length

A stride length defines the distance from a contact event of one foot to the subsequent contact event of that same foot (e.g. heel strike to heel strike). Stride length causes the major displacement of the body along the path of progression during a gait cycle; a complete gait cycle consists of one stride (Craik and Dutterer, 1995). Decreased stride length related to a poor gait pattern has been observed with stroke walkers compared to healthy subjects (Wooley, 2001). In the present studies, the values recorded for stride length for the healthy subjects were: right leg 125.7 cm (18.6) and left leg 128.7 cm (10.7), mean and (SD). The stride length values determined for the control and experimental groups are given in Table 3.25, with data separated according to experimental condition, side affected by stroke and fast/slow walker status.

Statistical analyses of the summed mean stride lengths for the three tests performed on the stroke subjects (control and experimental groups) identified significantly shorter stride lengths than for the healthy subjects ($p < 0.01$); the mean difference was 15.7 cm for the control subjects, 67.5 cm for the experimental subjects using shoes, and 62.0 cm for the experimental using a DAFO. The corresponding values for the control ($n = 3$) and experimental ($n = 10$) groups were also significantly different ($p < 0.05$), with shorter

stride lengths evident for the experimental group, in the DAFO and shoes-alone condition; the mean difference was 55.8 cm for the experimental group using shoes, and 53.0 cm for the experimental group using a DAFO.

Table 3.25 Stride length for both groups. The stride length (cm) data are average and (SD) of independent measurements recorded in the 3 testing sessions as described in Methods.

Stride length (cm)

	Affected side			**Unaffected side**		
	Test I	*Test II*	*Test III*	*Test I*	*Test II*	*Test III*
Control group (*n* = 3)	106.3 (3.7)	123.6 (10.1)	104.7 (34.6)	107.5 (9.8)	104.7 (11.1)	103.6 (12.1)
Exp group *(Fast)*						
Shoes (*n* = 5)	73.9 (17.8)	74.2 (7.0)	83.5 (9.4)	75.1 (11.3)	80.7 (12.8)	84.1 (17.2)
DAFO (*n* = 5)	79.4 (15.7)	84.7 (20.8)	85.7 (13.9)	77.2 (14.2)	78.9 (14.1)	84.2 (14.1)
Exp group *(Slow)*						
Shoes (*n* = 4)	36.9 (13)	38.5 (13)	37.9 (10.5)	42.1 (18.3)	36.3 (12.7)	34.2 (11.3)
DAFO (*n* = 5)	45.6 (24.2)	33.6 (6.9)	40.4 (8.0)	46.4 (21.8)	36.6 (12.7)	38.0 (7.0)

Further within-group (experimental) data analysis was undertaken. The individual difference of DAFO (D) minus shoes (S) stride length values for each experimental subjects, denoted as D1-S1 in Test I, D2-S2 in Test II, D3-S3 in Test III are shown in (Figure 3.19). In this figure, each data point represents stride length values for an individual subject. Values < 0.0 indicate results where stride length was longer with shoes, and values > 0.0 represent longer stride length with a DAFO.

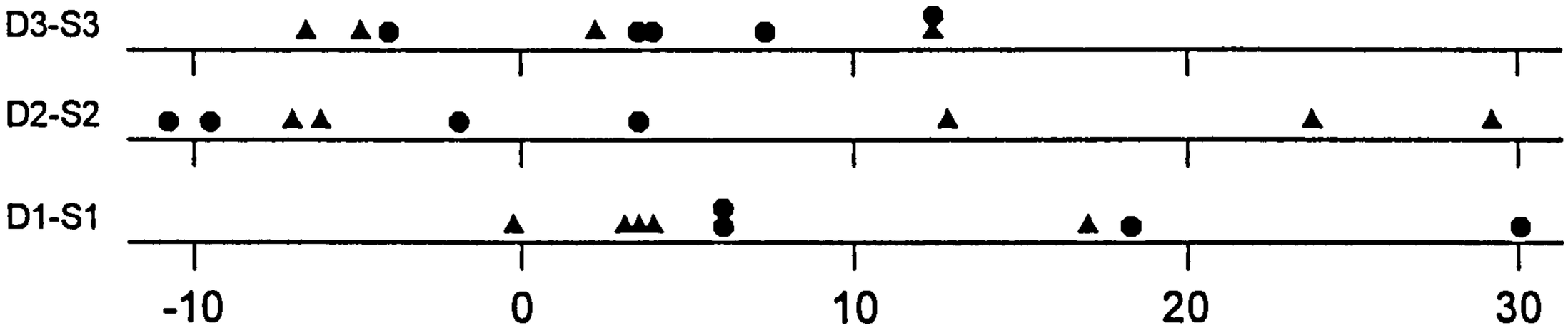


Figure 3.19 Differences in stride length (cm) between the DAFO (D) or shoe (S) condition for the experimental group. Each symbol represents an individual subject; triangles indicate fast walkers and circles indicate slow walkers. 1-3 denotes test number. The figures shown on the x-axis represent stride length in centimetres (cm). For further details, see text.

Comparisons (paired *t*-tests) of the differences for each pair of measurements for experimental subjects (n = 9) revealed a significantly longer stride length in the DAFO condition compared to shoes in test I (p = 0.018). The difference of the stride length using DAFOs compared using shoes in test I was 9.72 cm; 95 % CI indicated substantial variability 2.13, 17.30. More consistent values were obtained for test II and test III and longer stride lengths were evident using shoes, although these differences did not achieve statistical significance (test II, p = 0.465; test III, p = 0.238). No statistically significant differences in values between experimental conditions were detected on the side unaffected by stroke. Differences in stride length apparent following separation of data according to fast/slow walker status also failed to achieve statistical significance (Table 3.26).

Table 3.26 Summary of statistical tests (paired *t*-tests) on stride length determinations for the experimental group according to fast (*n* = 5) and slow (*n* = 4) walkers' status on the affected side.

Group/ test	Mean	95.0% CI	*p*
Fast/ test I	5.47	(-2.93, 13.87)	0.145
Fast/ test II	10.47	(-10.14, 31.09)	0.231
Fast/ test III	2.20	(-7.70, 12.09)	0.571
Slow/ test I	15.03	(-3.17, 33.23)	0.078
Slow/ test II	-4.61	(-15.19, 5.96)	0.259
Slow/ test III	4.01	(-6.78, 14.81)	0.322

Step length

The step length (cm) is the linear distance between two consecutive contralateral contacts of the legs. When defining step length, reference is made to the advancing limb. For example, the distance from initial contact (heel strike) of the left foot to initial contact of the right foot is a right step length (Craik and Dutterer, 1995). Reduced step length was shown to be a feature of inadequate gait ability for stroke patients compared to healthy subjects (Diamond and Ottenbacher, 1990). In the present studies, in the healthy subject group (*n* = 4), the mean and (SD) values recorded for step length were 63.5 cm (18.7) for the right leg and 62.2 cm (16.9) for the left leg. These data are consistent with earlier studies of healthy young and aged subjects (Öberg *et al.*, 1993; Stolze *et al.*, 1998).

The step length measurements recorded for the control and experimental groups are given in Table 3.27; data are separated according to experimental condition, affected side and fast/slow walker status. The mean step lengths, from the three tests performed using stroke subjects (control, *n* = 3 and experimental groups, *n* = 10) on the affected side, were significantly shorter ($p < 0.05$) than for the healthy subjects; the mean difference was 7.3 cm for the control subjects, 37.8 cm for the experimental subjects

using shoes, and 37.6 cm for the experimental using a DAFO. The relative order of mean step length was healthy subjects > control subjects > experimental subjects (Bonferroni's multiple comparison post-test). The corresponding values of the control (n = 3) and experimental groups (n = 10) were also significantly different ($p < 0.05$), with a shorter mean step length evident for the experimental group; the mean difference was 30.5 cm for the experimental group using shoes and using a DAFO.

Table 3.27 Step length (cm) from both groups. The step length data are average and (SD) of independent measurements recorded in the 3 testing sessions as described in Methods.

	Step length (cm)					
	Affected side			**Unaffected side**		
	Test I	*Test II*	*Test III*	*Test I*	*Test II*	*Test III*
Control group (*n*=3)	57.6 (7)	59.6 (22.9)	49.5 (11.1)	51.9 (11.5)	59.5 (9.4)	64.8 (16.7)
Exp group *(Fast)*						
Shoes (*n=5)*	25.8 (18.4)	31.8 (19.3)	30.7 (21.5)	51.6 (10.7)	47.4 (17.5)	50.8 (17.8)
DAFO (*n=5)*	28.3 (21.6)	28.9 (23.8)	31.2 (17.8)	48.6 (8.7)	53.2 (11.4)	54.8 (10.8)
Exp group (*Slow)*						
Shoes (*n=4)*	17.1 (11.2)	21.4 (14.9)	17.8 (14.5)	33.1 (18.3)	40.2 (20.3)	22.3 (17.7)
DAFO (*n=5)*	18.7 (6.9)	20.0 (10.8)	24.8 (7.0)	32.1 (29.7)	22.6 (17.2)	21.9 (15.1)

Within-group (experimental) data analyses for the DAFO and shoe conditions were examined and are presented in Figure 3.20. As earlier, data are given for the three tests and as the individual difference of DAFO (D) minus shoe (S) step length values for each

subject, denoted as D1-S1, D2-S2 and D3-S3. Here, values < 0.0 represent results where step length increased using shoes, and values > 0.0 indicate an increase in step length using DAFOs.

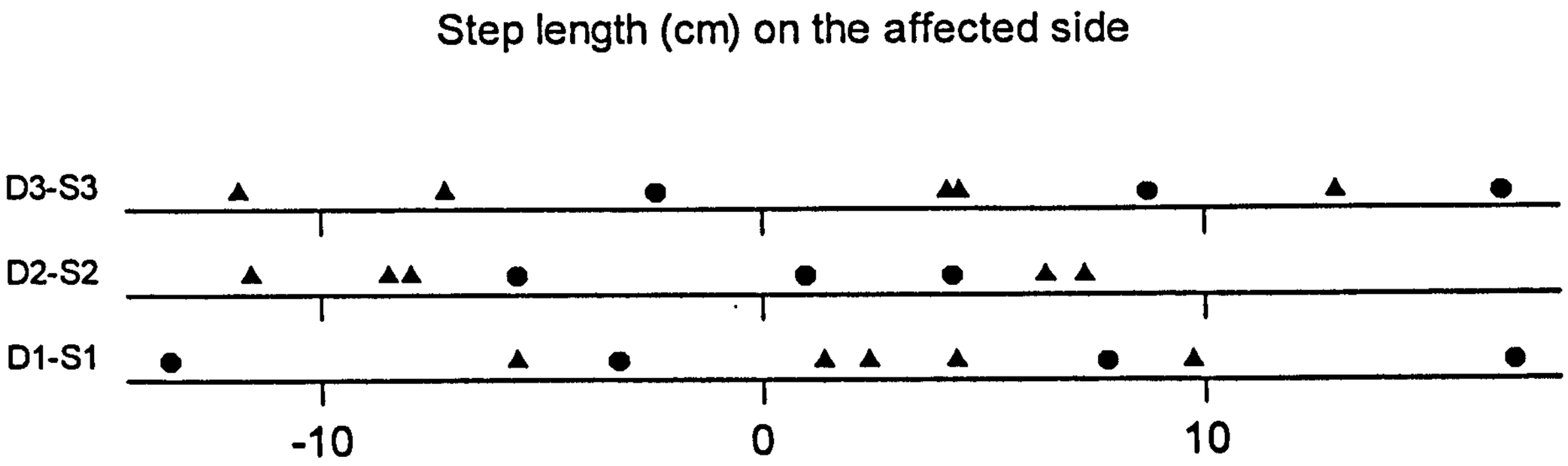


Figure 3.20 Differences in step length between the DAFO (D) or shoe (S) condition for the experimental group. Each symbol represents an individual subject; triangles indicate fast walkers and circles indicate slow walkers. 1-3 denotes test number. The step length shown on the x-axis represents step length in centimetres (cm). For further details, see text.

Comparison of each pair of measurements in the experimental group (n = 9) with paired t-tests indicated no statistically significant differences over the three separate tests (p = 0.474 in test I, p = 0.508 in test II, p = 0.389 in test III). There were also no statistically significant differences detected between the DAFO and shoe condition on the side unaffected by stroke, or when data were categorized according to subjects' walking speed (Table 3.28). The large variability of these data is apparent in the CI values, which may be a function of the limited number of subjects involved in the study.

Table 3.28 Summary of statistical tests (paired *t*-tests) on step length determinations for the experimental group according to fast and slow walkers' status on the affected side.

Group/ test	**Mean**	**95.0% CI**	***p***
Fast/ test I	2.46	(-4.41, 9.33)	0.376
Fast/ test II	-2.88	(-14.05, 8.29)	0.514
Fast/ test III	0.52	(-11.88, 12.92)	0.913
Slow/ test I	2.00	(-19.09, 23.09)	0.783
Slow/ test II	-0.10	(-12.62, 12.42)	0.976
Slow/ test III	7.67	(-16.16, 31.49)	0.300

Cadence

Cadence is the rhythm of the walking pattern and is defined as the number of steps taken per unit of time (step/min) (Bohannon, 1997). A reduced cadence was reported for stroke patients with limited gait ability, and positive changes in this variable occurred following DAFO use by hemiparesis subjects (Dieli *et al.*, 1997). In the present studies, in the healthy subject group, the mean and (SD) values for cadence recorded separately for each leg were 116.6 step/min (4.8) for the right leg and 114.6 step/min (5.2) for the left leg. The mean and SD of the cadence calculated for the control and experimental subjects are given in Table 3.29.

It was determined (one factor ANOVA) that the mean cadences from the three tests performed using stroke subjects (control, $n = 3$ and experimental groups, $n = 10$) were significantly less than ($p < 0.05$) those obtained from the healthy subjects; the mean difference was 27.6 steps/min for the control subjects, 49.2 steps/min for the experimental subjects using shoes, and 48.4 steps/min for the experimental using a DAFO. The corresponding values of the control and experimental groups were also significantly different ($p < 0.05$) with reduced cadence evident for the experimental

group; the mean difference was 21.6 steps/min for the experimental group using shoes, and 20.8 steps/min for the experimental group using a DAFO.

Table 3.29 Cadence from both groups. Cadence (steps/min) data are mean and (SD) of independent measurements recorded in the 3 testing sessions as described in Methods

	Cadence (steps/min)					
	Affected side			**Unaffected side**		
	Test I	*Test II*	*Test III*	*Test I*	*Test II*	*Test III*
Control group (*n*=3)	86.4 (18)	88.2 (10.7)	89.5 (13.5)	90.4 (21)	94.5 (11)	93.3 (9)
Exp group *(Fast)*						
Shoes (*n=5)*	74.2 (7.6)	76.4 (13)	72 (13.6)	78.4 (5)	78.4 (8.3)	73.9 (5.8)
DAFO (*n=5)*	76.9 (7.5)	81 (9)	77.5 (9.6)	75.9 (7.3)	82.2 (8)	78.6 (9.2)
Exp group (*Slow)*						
Shoes (*n=4)*	53.6 (9.4)	57.6 (12.7)	62.9 (16)	57.2 (14.4)	55 (12)	63.9 (17)
DAFO (*n=5)*	59.7 (11)	55.9 (13)	56.7 (13.8)	59 (14.2)	55.4 (14.1)	56.1 (13.4)

Within-group (experimental) data analyses for the DAFO and shoe conditions were examined and are presented in Figure 3.21. As earlier, data are given for the three tests and as the individual difference of DAFO (D) minus shoe (S) cadence values for each subject, denoted as D1-S1, D2-S2 and D3-S3. Here, values < 0.0 represent results where cadence increased using shoes, and values > 0.0 where cadence increased using DAFOs.

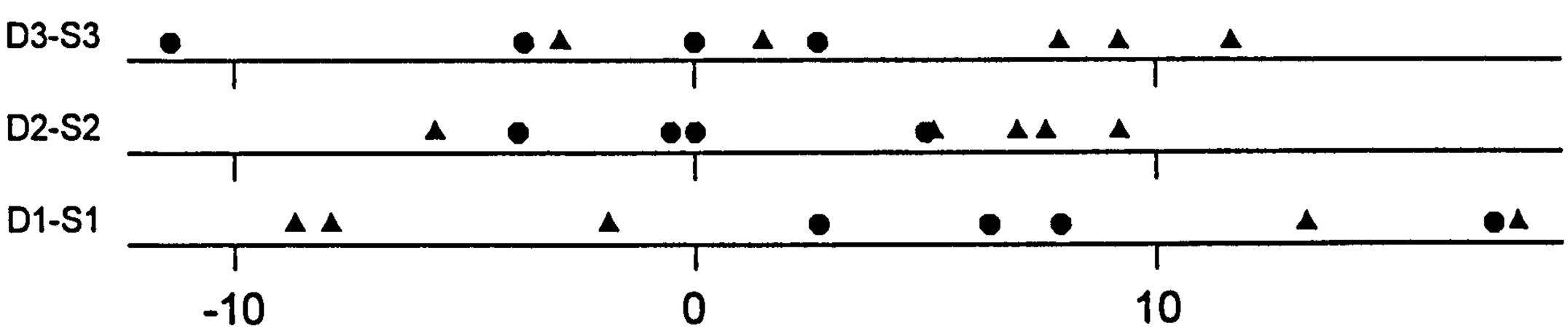


Figure 3.21 Differences in cadence between the DAFO (D) or shoe (S) condition for the experimental group. Each symbol represents an individual subject; triangles indicate fast walkers and circles indicate slow walkers. 1-3 denotes test number. The cadence values shown on the x-axis represent cadence in steps per minutes (steps/min). For further details, see text.

Comparison of each pair of measurements within the experimental group (n = 9) with paired t-tests indicated no statistically significant differences over the three separate tests (p = 0.157 in test I, p = 0.168 in test II, p = 0.512 in test III). There were also no statistically significant differences detected between the DAFO and shoe condition on the side unaffected by stroke, or when data were categorized according to subjects' walking speed (Table 3.30).

Table 3.30 Summary of statistical tests (paired t-tests) on cadence determinations for the experimental group according to fast and slow walkers' status on the affected side.

Group/ test	**Mean**	**95.0% CI**	***p***
Fast/ test I	2.50	(-12.73, 17.73)	0.672
Fast/ test II	4.68	(-2.67, 12.03)	0.152
Fast/ test III	5.46	(-1.97, 12.89)	0.111

Slow/ test I	8.57	(-1.31, 18.46)	0.070
Slow/ test II	0.18	(-5.60, 5.95)	0.929
Slow/ test III	-3.10	(-12.84, 6.64)	0.386

Single stance (support) phase

During a typical gait cycle, the two periods of stance- and swing-phase overlap with each another. Double and single support phases (as opposed to stance and swing of one limb) characterise the co-ordination between the legs during the gait cycle. The instance when one leg is the only point of contact with the walking surface is termed single-support. One gait cycle has two single-support times (i.e. one per leg). Consequently, leg support and contralateral swing time are equal (Murray, 1967). The single limb support is possibly the best indicator of the limb's support capability, and has shown to been to be shortened (clearly) in stroke subjects (De Quervain *et al.*, 1996; Dieli *et al.*, 1997).

In the healthy subject group, the mean and (SD) values for the duration of single stance phase (expressed as a percentage of the duration of the gait cycle) recorded simultaneously for each leg, were 40.6 % (6.4) (right leg) and 39.2 % (2.4) (left leg). The values for the control and experimental groups are presented in Table 3.31, with data separated according to experimental condition, side affected by stroke and fast/slow walker status. Statistical analyses of the summed mean single stance phase for the three tests performed on the stroke subjects (control and experimental groups) identified significantly shorter ($p < 0.05$) single stance phase than for the healthy subjects; the mean difference was 7.1 % for the control subjects, 17.5 % for the experimental subjects using shoes, and 17.7 % for the experimental using a DAFO. Bonferroni's post-test indicated that the relative order of single stance phase duration was healthy subjects > control subjects > experimental subjects.

The corresponding values for the control (n = 3) and experimental (n = 10) groups were also significantly different ($p < 0.05$), with shorter single stance phase evident for the experimental group, in the DAFO and shoes-alone condition; the mean difference was 10.4 % for the experimental group using shoes, and 10.6 % for the experimental group using a DAFO.

Table 3.31 Single stance phase of control and experimental groups in the three tests; mean and (SD). Single stance phase from the full gait cycle are presented as %.

Single stance phase duration (% of duration of gait cycle)						
	Affected side			**Unaffected side**		
	Test I	*Test II*	*Test III*	*Test I*	*Test II*	*Test III*
Control group (n = 3)	33.8 (6.8)	32.0 (9.5)	32.7 (7.3)	32.2 (10.5)	31.2 (10.9)	30.2 (13.2)
Exp group *(Fast)*						
Shoes (n = 5)	25.4 (3.5)	28.7 (2.8)	27.2 (4.5)	37.2 (7.8)	35.9 (6.0)	36.8 (8.6)
DAFO (n = 5)	25.7 (2.7)	26.6 (3.4)	28.4 (5.5)	33.8 (6.6)	35.7 (3.1)	36.8 (7.4)
Exp group (*Slow*)						
Shoes (n = 4)	14.2 (9.2)	14.6 (5.7)	18.9 (6.1)	24.9 (14.1)	29.2 (10.5)	30.1 (9.8)
DAFO (n = 5)	17.1 (2.7)	17.4 (10)	19.0 (5.6)	28.0 (11.8)	28.2 (15.2)	32.1 (8.5)

Within-group (experimental) data analyses were undertaken as indicated earlier (Figure 3.22). In this figure, each data point represents single stance phase values for an individual subject. Values < 0.0 represent results where single stance phase was longer with shoes, and values > 0.0 represent longer single stance phase with DAFOs. Normal,

healthy subjects' single stance phase averages approximately 40 % of the full gait cycle.

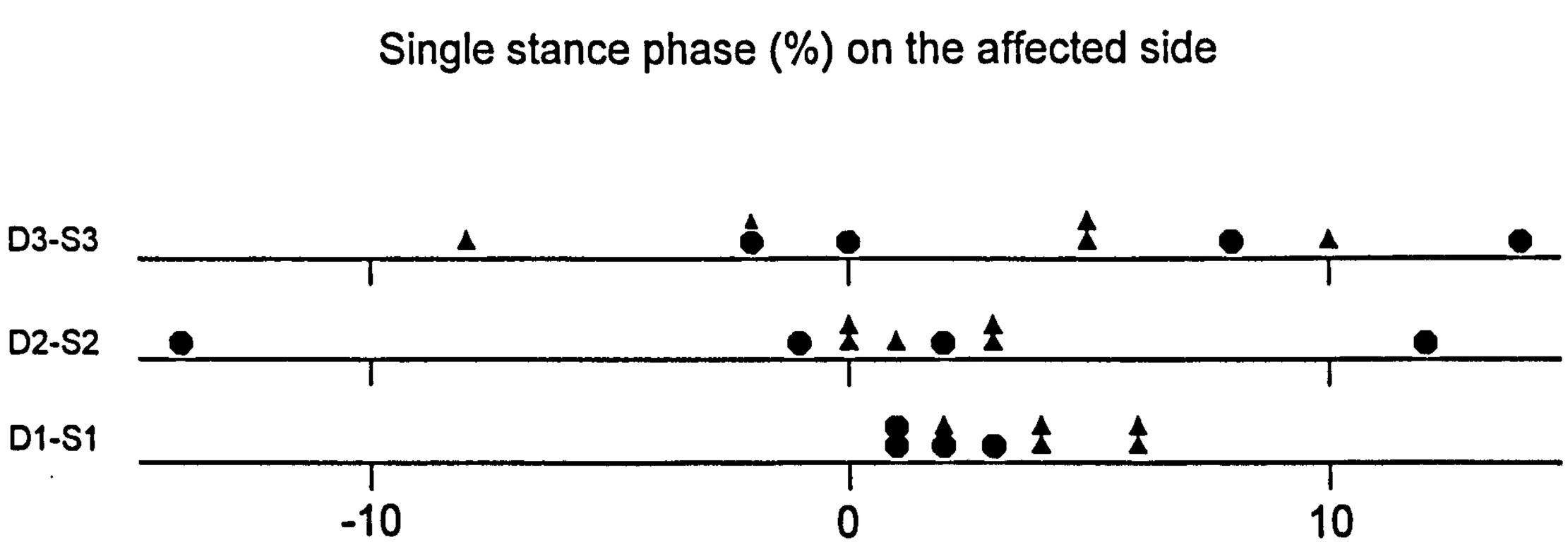


Figure 3.22 Differences in single stance phase duration (%) between the DAFO (D) or shoe (S) condition for the experimental group. Each symbol represents an individual subject; triangles indicate fast walkers and circles indicate slow walkers. 1-3 denotes test number. The single stance phase values shown on the x-axis represent single stance phase in percents (%) For further details, see text.

Comparisons (paired *t*-tests) of the differences for each pair of measurements for experimental subjects (n = 9) revealed a significantly longer single stance duration in the DAFO condition compared to shoes in test I (p = 0.01) but not in test II (p = 0.773) or test III (p = 0.186). The single stance duration increased 3.22 % using DAFOs compared using shoes in test I, but 95 % CI values varied 1.745, 4.700. In contrast, there were no statistically significant differences detected in single stance duration between experimental conditions on the unaffected side (test I, p = 0.06; test II, p = 0.234; test III, p = 0.064).

Further analyses based on the fast (n = 5) and slow (n = 4) walker classification revealed a statistically significant difference in single stance duration for both the fast (p = 0.004) and slow walkers (p = 0.035) in test I, but not in tests II and III (Table 3.32). The single stance phase increased 4.40 % for fast walkers, and 1.75 % for slow walkers using DAFOs compared to using shoes on the side affected by stroke. Once again, the CI for these data indicated considerable variability. There was no evidence for statistically significant differences in single stance duration on the side unaffected by stroke.

Table 3.32 Summary of statistical tests (paired t-tests) on single stance duration for the experimental group according to fast (n=5) and slow (n=4) walkers' status on the affected side.

Group/ test	**Mean**	**95.0% CI**	***p***
Fast/ test I	4.40	(2.322, 6.478)	0.004**
Fast/ test II	1.40	(-0.483, 3.283)	0.108
Fast/ test III	2.00	(-6.74, 10.74)	0.560
Slow/ test I	1.75	(0.227, 3.273)	0.035*
Slow/ test II	-0.25	(-17.31, 16.81)	0.966
Slow/ test III	5.00	(-6.77, 16.77)	0.269

* $p < 0.05$, ** $p < 0.01$.

3.3.1.4 Segments kinematics of gait cycle

A major aim of the research was to evaluate the effects of DAFOs on lower limb (joint) kinematics during stroke patients' gait. For these investigations, the subjects' gait was measured by analysing the angular displacement of the foot, shank and thigh segments, during two strides, in the sagittal plane, and for the affected and unaffected leg. These studies utilized the 3-D movement analysis methods described earlier, except that the saggital plane was only used in this main phase of the analysis, after the

reliability tests (section 3.1.1.3). To enable direct comparisons between subjects' segmental motions during stance and swing phases, all segmental kinematic parameters were normalised to 100 % of the gait cycle length.

During data analyses of subjects' stance and swing phases, the peak (minimum and maximum) values of the various segmental parameters were considered, because these limits of the joints' motions have been shown to be informative for describing the human gait pattern and its changeability (Winter, 1990; Wu, 1995b; Enoka, 2002). The minimum value of thigh velocity was determined during mid stance phase, to specify the level of stability of the more proximal joints (Wu, 1995a; De Quervain *et al.*, 1996). The minimum value of thigh displacement was obtained at the end of stance (push-off) phase, to define the control and flexibility of the lower limb joints, when the direction of hip joint movement changes in this critical component of pre-swing phase (De Quervain *et al.*, 1996; Enoka, 2002). The minimum values of foot and shank displacement and velocities, and the maximum value of thigh velocity were determined during early swing (toe-off) phase, because of the associated with large ankle plantarflexion and knee extension (Lehmann *et al.*, 1987; De Quervain *et al.*, 1996; Olney and Richards, 1996). The maximum values of foot and shank velocity were determined during the middle of swing phase. These maximum angular velocity values are relevant to large ankle and knee flexion motions, when joints movements are changing direction, and are critical to take a step forward successfully (Roberts *et al.*, 1997; Wooley, 2001; Lamontagne *et al.*, 2002). In subsequent analyses, the fast/slow walker categorization described earlier was also used here in an effort to maintain consistency between experimental group subjects.

Minimum foot displacement

Foot angular displacement (degrees) measurements during a gait cycle provide an indication of the changes of the angular position of the foot segment in space (global reference frame). Although the angle obtained was not the actual joint angle, it

effectively reflects angle changes of the ankle joint (flexion-extension) movements (van Vliet, 1988; Winter, 1990). The foot segment data were derived from coordinate data of the forefoot and ankle. The results of the foot displacement investigations for a full gait cycle from the affected side of the stroke subjects are shown in Figure 3.23 a-c. For comparative purposes, the average healthy subjects' (n = 4) foot displacement data are also included (red traces).

For the healthy subjects, the averaged values for foot angular displacement recorded simultaneously for each leg indicated a small difference between left and right sides, which is consistent with earlier reports where angular displacement data for both legs were summated (Murray, 1967). Studies of these healthy subjects (Figure 3.23, red traces) showed that the foot angular displacement in the saggital plane increased during the heel strike (to 171°), and then began to decrease, due to the load on the foot. In the mid-stance phase, foot angulations remained steady (about 157°), and then decreased prior to the push-off phase.

The minimum foot angular displacement was achieved during early swing phase (84°) when the ankle joint achieves maximum extension, and before foot motion begins to increase, as the ankle joint rotates to flexion during the mid and end components of the stance phase. The period between the end of stance phase and early swing phase is critical, as during this push- off phase, weight is transferred over to the other leg, and toe release from the floor occurs (minimum foot angular displacement). This requires fine dynamic balance control of lower limb joints, (Lehmann *et al.*, 1987; De Quervain *et al.*, 1996; Olney and Richards, 1996; Whittle, 1998). Here, it should be noted that lower minimum (numerical) values correspond to better (nearer normal) foot angulations.

Foot angular displacement data are shown graphically in Figure 3.23, which suggests that the averaged data obtained for the control (n = 3,) and experimental (fast walkers, n = 5 and slow walkers, n = 5) groups followed a similar pattern to that of the healthy

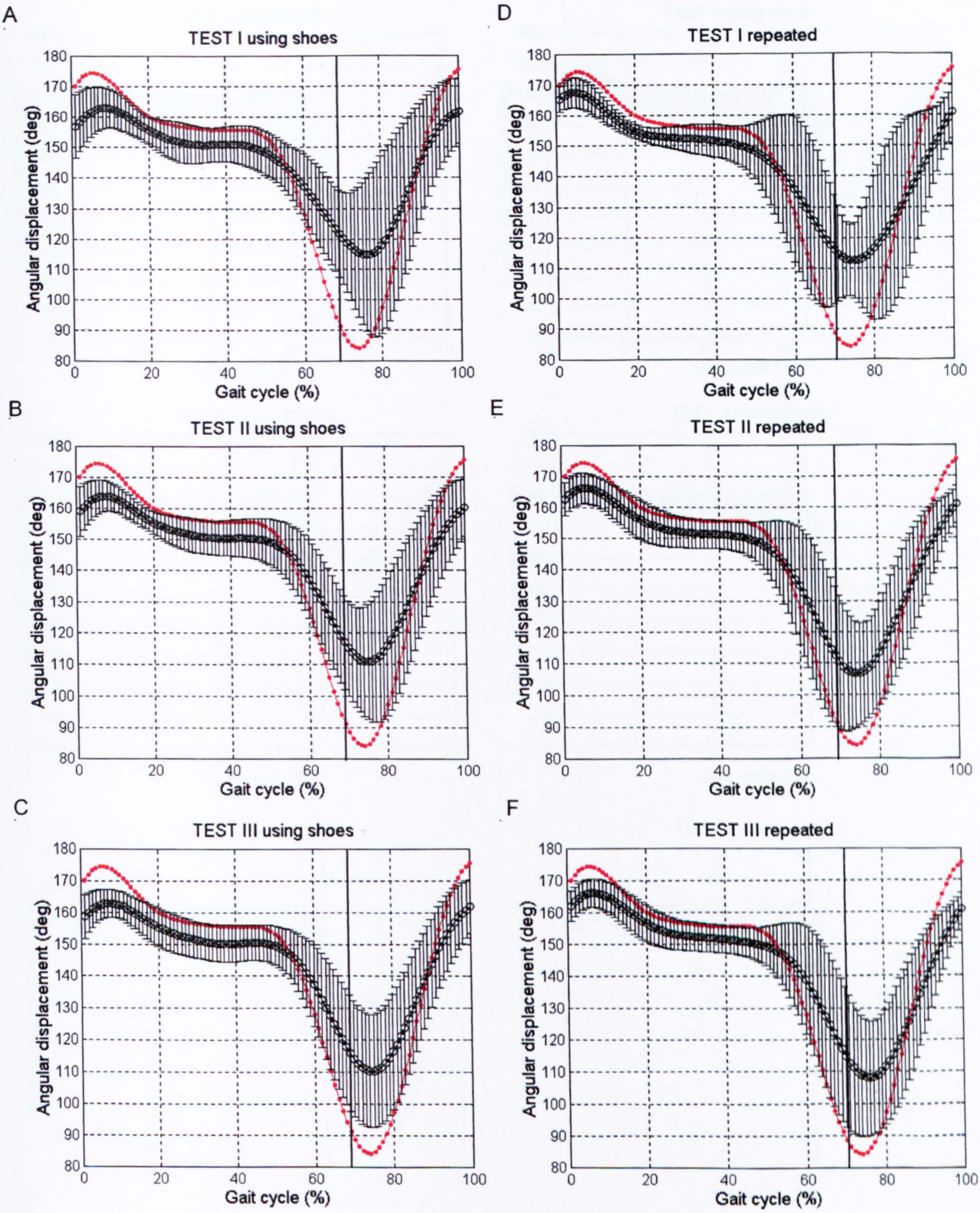
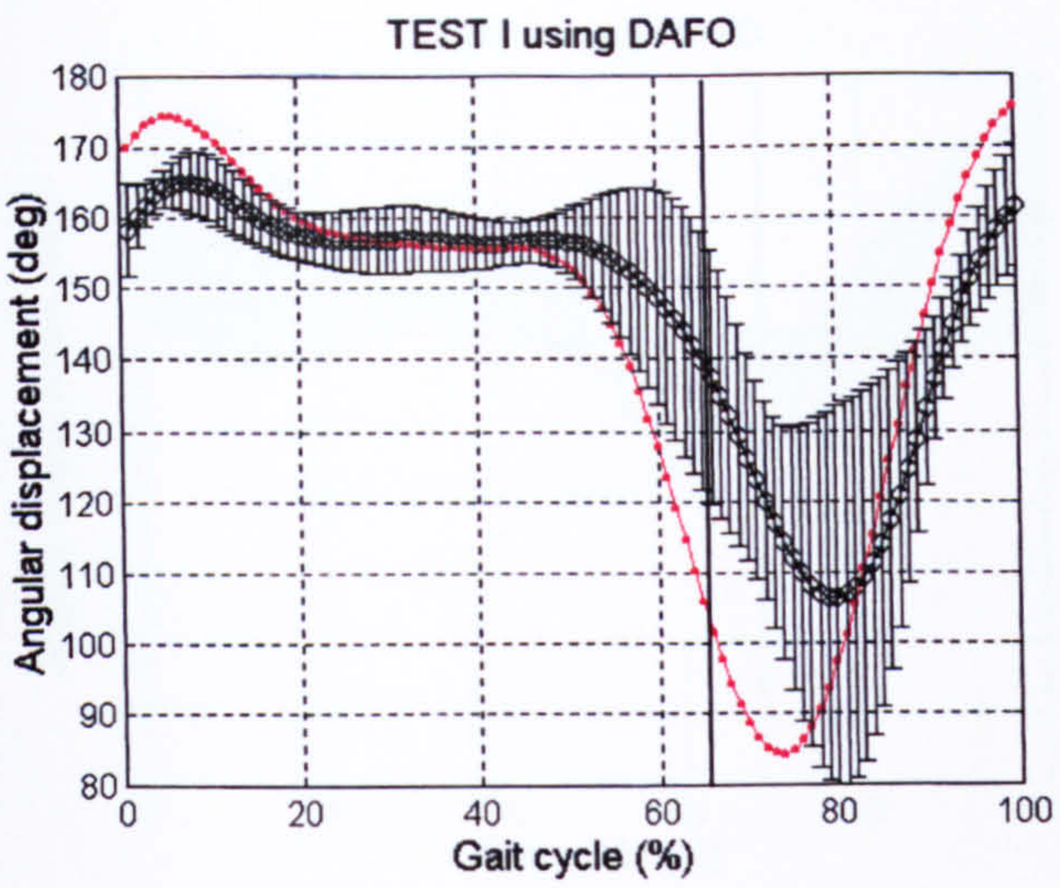
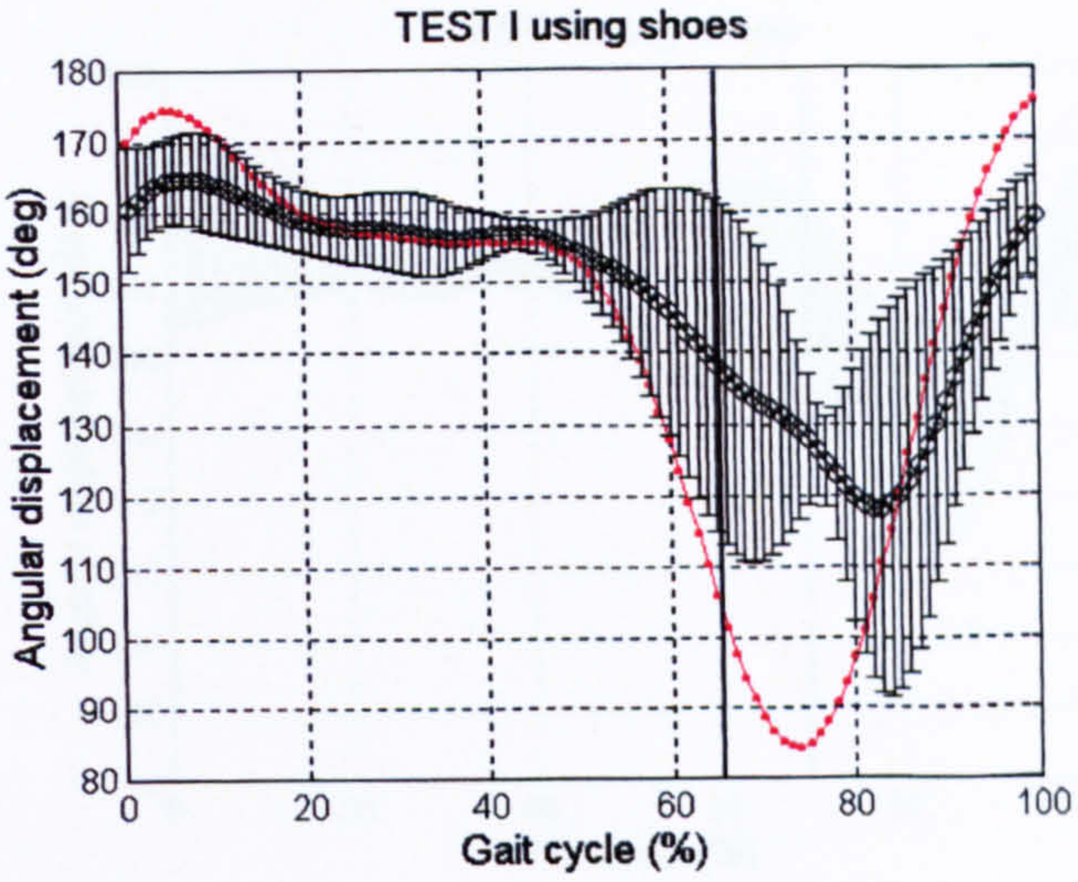
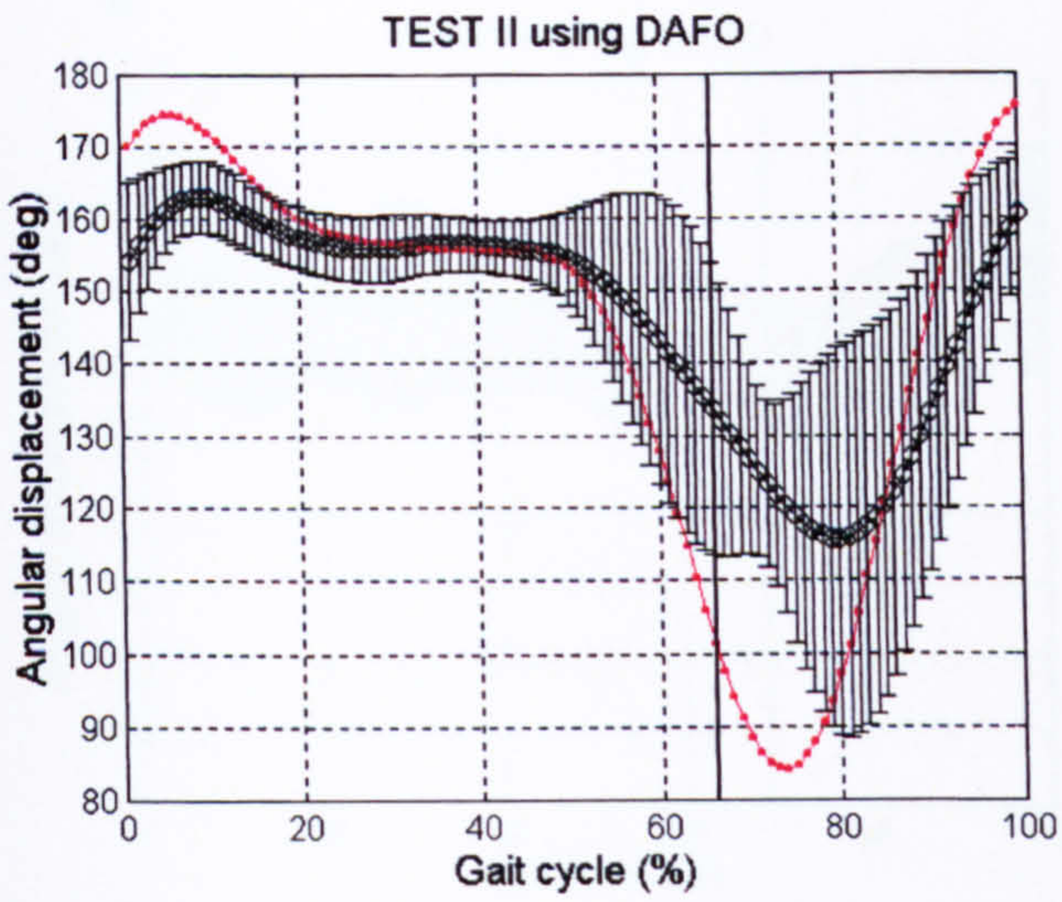


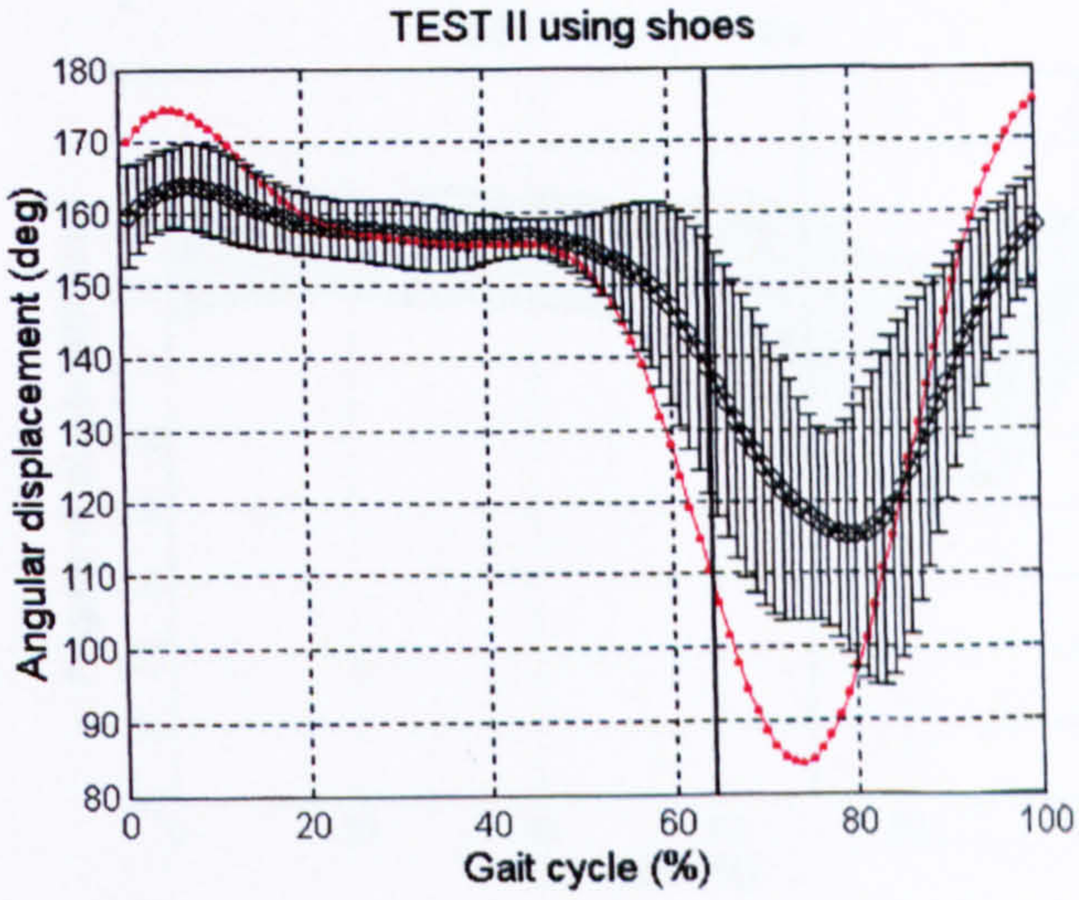
Figure 3.23 a Foot angular displacement of control subjects (n = 3): affected side

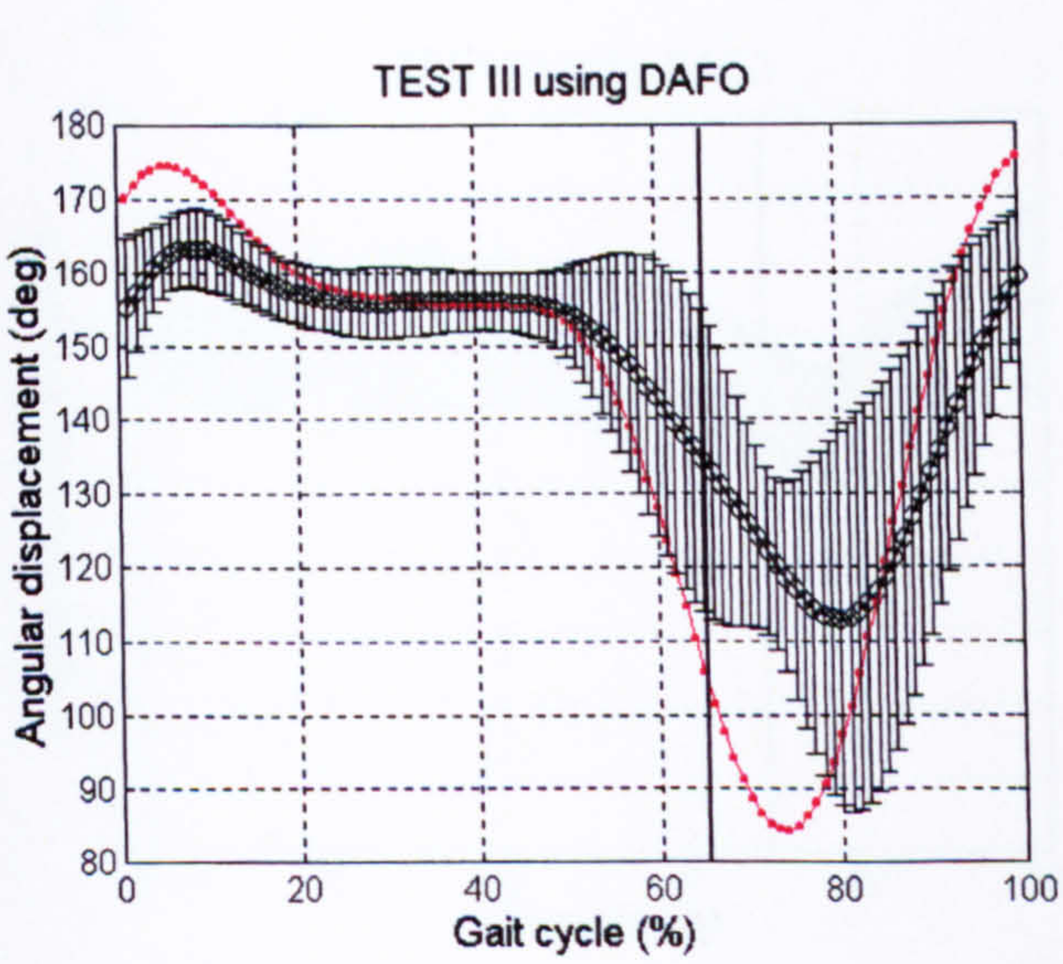
Values are shown for trial I (A-C) and trial II (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.











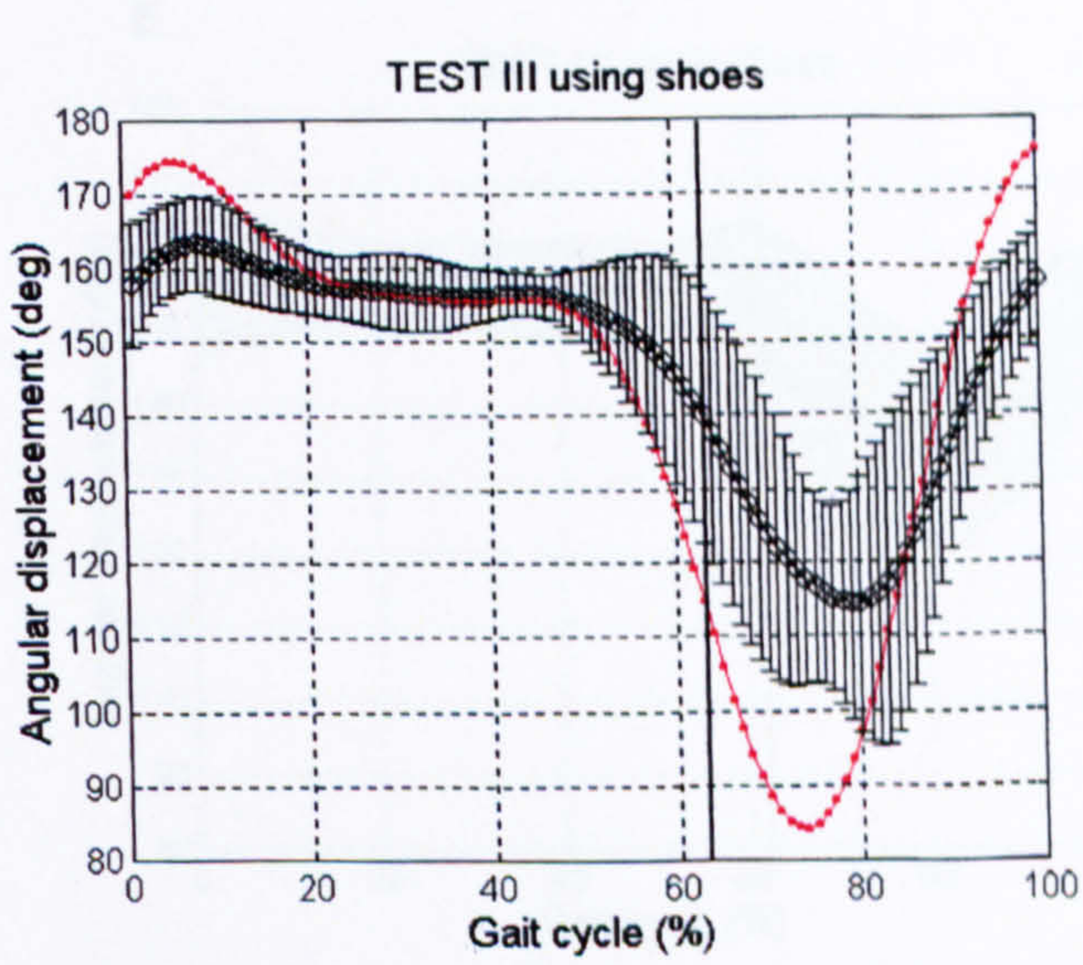


Figure 3.23 b Foot angular displacement of **fast** walkers (n = 5): affected side

Values are shown using DAFO (A-C) and using shoes (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

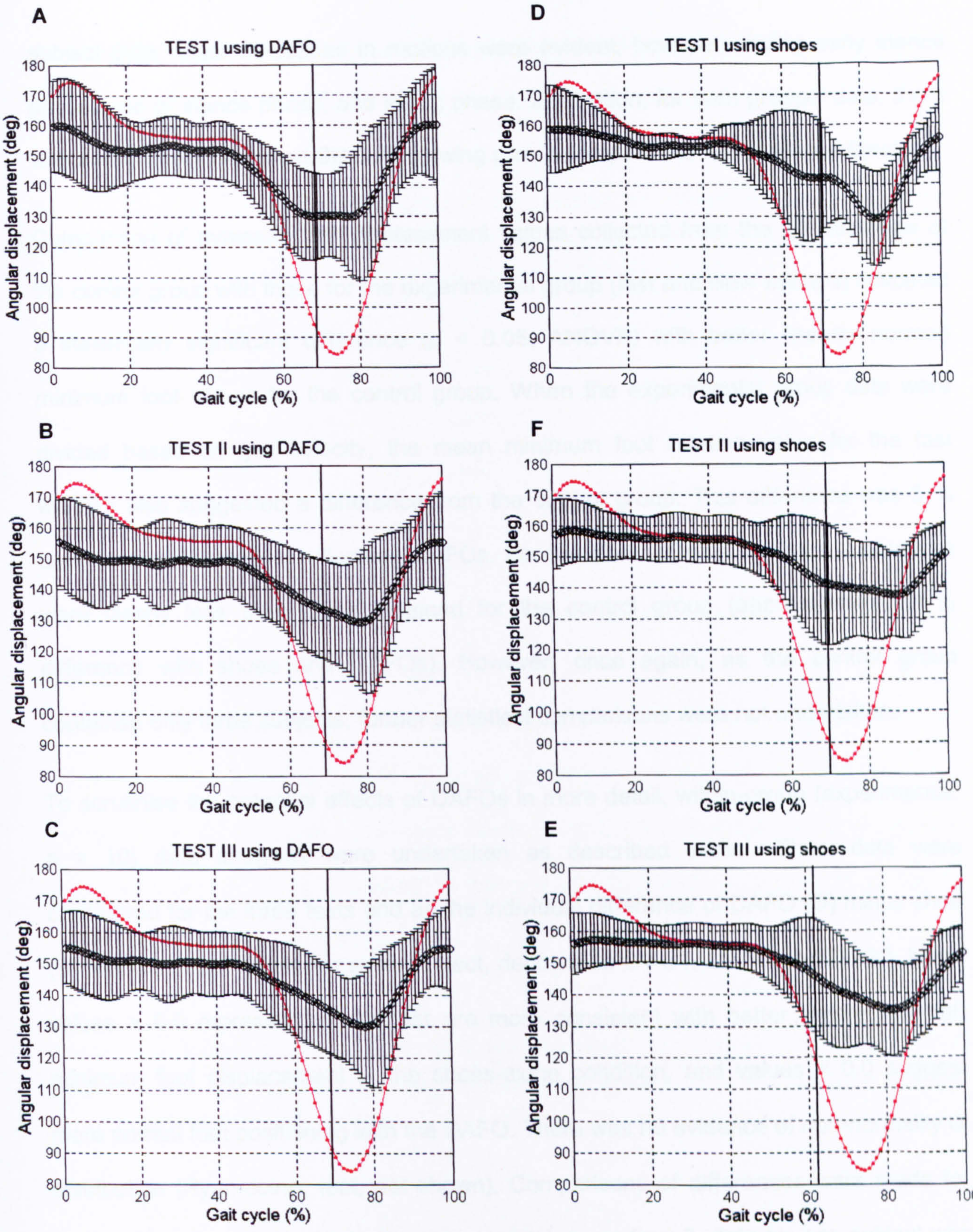


Figure 3.23 c Foot angular displacement of **slow** walkers: affected side

Values are shown using DAFO (A-C, n = 5) and using shoes (D-F, n = 4) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

subject data. Clear decreases in motions were evident, however, during early stance phase, end of stance phase, and swing phase. In addition, for both groups' data, there was a noticeably increased SD during swing phase compared to the healthy subjects.

Comparison of minimum foot displacement values collected from the affected side of the control group with those for the experimental group (fast and slow walkers) indicated a statistically significant difference ($p < 0.05$, ANOVA) with better (nearer normal) minimum foot values for the control group. When the experimental group data were divided based on gait velocity, the mean minimum foot rotation value for the fast walkers also suggested a difference from the control group. This difference was 5 % using shoes, but only 1.1 % using DAFOs. For the slow walkers, the minimum values were clearly less than those obtained for the control group (approximately 20 % difference with shoes and DAFOs). However, once again, as the control group contained only three subjects, further statistical comparisons were not undertaken.

To scrutinise the potential effects of DAFOs in more detail, within-group (experimental, $n = 10$) data analyses were undertaken as described earlier. Thus, data were considered for the three tests and as the individual difference of DAFO (D) minus shoe (S) foot minimum values for each subject, denoted as D1-S1, D2-S2 and D3-S3. Here, values > 0.0 represent results that are more consistent with better (nearer normal) minimum foot displacement in the shoes-alone condition, and values < 0.0 suggest more normal foot positioning with the DAFO. There was no evidence of non-normality of distribution (Ryan-Joiner test, not shown). Comparisons of differences were made for each paired measurements in the experimental group ($n = 9$, data for one subject was unavailable due to a total lack of confidence when walking without the DAFO). Paired *t*-tests indicated no statistically significant difference between the values recorded for the DAFO and shoes conditions on the subjects' side affected by stroke (Table 3.33). The CI for these data indicated considerable variability between subjects, which perhaps

may also be due to the limited number of subjects in these studies, the variation in gait velocity apparent and/or reliability limitations of the movement analysis procedures.

Table 3.33 Summary of statistical tests (paired *t*-tests) on differences of minimum foot displacement determinations for the experimental (Exp) group (n = 9). Comparisons are of minimum values recorded when subjects used shoes and a DAFO (affected side).

Group/ test	**Mean**	**95 % CI**	***p***
Exp/ Test I	-3.54	(-10.36, 3.28)	0.265
Exp/ Test II	0.66	(-8.05, 9.37)	0.866
Exp/ Test III	-2.00	(-8.51, 4.51)	0.498

Subsequent analyses based on the fast (n = 5) and slow (n = 5) walker classification revealed no significant difference ($p > 0.05$) in minimum foot displacement values using DAFOs compared to using shoes over the three tests during the 12 weeks testing trial (Table 3.34). It is interesting to note that the mean values shown are progressively more negative over the three tests (over the three months testing period) for the fast walkers. However, the CI for these data reveal large variability and overlap between subjects, which suggests that this is unlikely to indicate of any real improvement in values for DAFO users as opposed to shoe users.

Table 3.34 Summary of statistical tests (paired *t*-tests) on minimum foot displacement determinations within the experimental group according to fast (n = 5) and slow (n = 4) walker status on the affected side.

Group/ test	**Mean**	**95 % CI**	***p***
Fast/ Test I	-6.13	(-18.23, 5.97)	0.232
Fast/ Test II	-3.52	(-14.58, 7.54)	0.427
Fast/ Test III	-5.09	(-14.87, 4.69)	0.222
Slow/ Test I	-0.30	(-12.42, 11.81)	0.942
Slow/ Test II	5.89	(-14.92, 26.69)	0.434
Slow Test III	1.86	(-11.70, 15.42)	0.692

Differences between values for DAFO and shoes minimum foot displacement on the side unaffected by stroke were not statistically different ($p < 0.05$, data not shown). For all groups, the unaffected side values were substantially better compared to those obtained for the affected side. In the control group, the minimum foot displacement values were 11.6 % lower on the unaffected than the affected side. In the experimental fast walkers, the unaffected side values were 15.4 % better using shoes and 11 % using DAFOs , and 9.3 % using shoes and 11.8 % using DAFOs with the slow walkers.

Minimum shank displacement

Determination of subjects' shank motion (the angular displacement of the shank segment in space, which reflects the angle changes of the knee joint (flexion-extension movements) was derived from coordinate data of the ankle and knee markers. The results of the full shank displacement investigations of a complete gait cycle are illustrated in Figure 3.24 a-c. The healthy subjects' shank displacement motion in the saggital plane increased during the heel strike phase (105°), and then began to decrease coincident with foot loading in stance phase. This decrease continued throughout the mid-stance and push-off phases, achieving minimum shank angular displacement during the early swing phase (35°, knee at maximum extension). Subsequently, the shank motion began to increase and regain maximum levels, as the knee joint rotated from flexion to extension during the mid- and late-swing phases (Figure 3.24, red traces).

The profile of the shank angular data for the control (Figures 3.24 a) and experimental (Figure 3.24 b - 3.24 c) groups indicated a similar pattern to that of the healthy subjects, although clear increases in variation of shank motion were apparent during the swing phase. In addition, all patients groups (control, $n = 3$ and experimental fast, $n = 5$ and slow, $n = 5$ walkers) demonstrated clear data variation (± SD) on the affected side compared to the unaffected side.

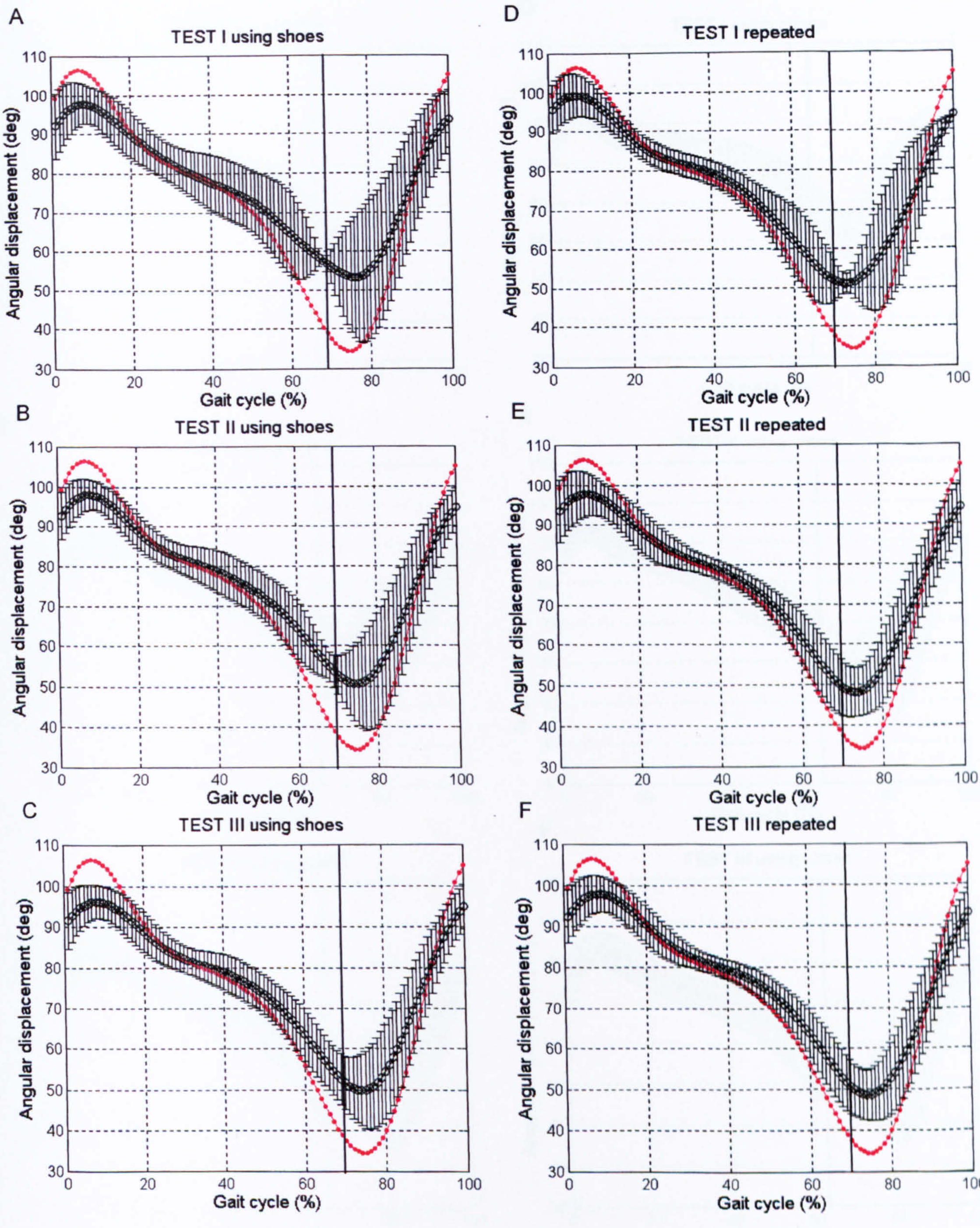


Figure 3.24 a Shank angular displacement of control subjects (n = 3): affected side

Values are shown for trial I (A-C) and trial II (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

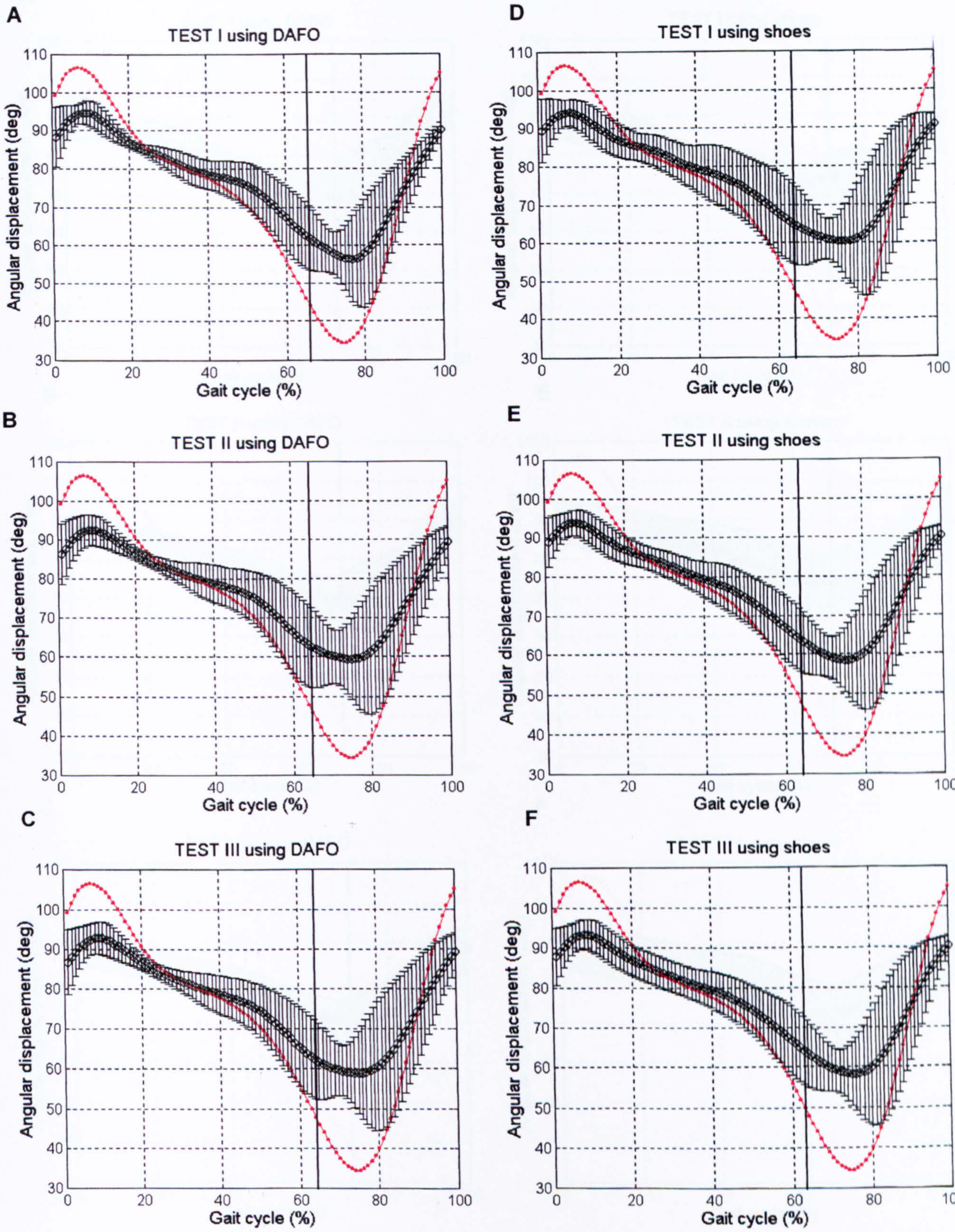


Figure 3.24 b Shank angular displacement of **fast** walkers (n = 5): affected side

Values are shown using DAFO (A-C) and using shoes (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

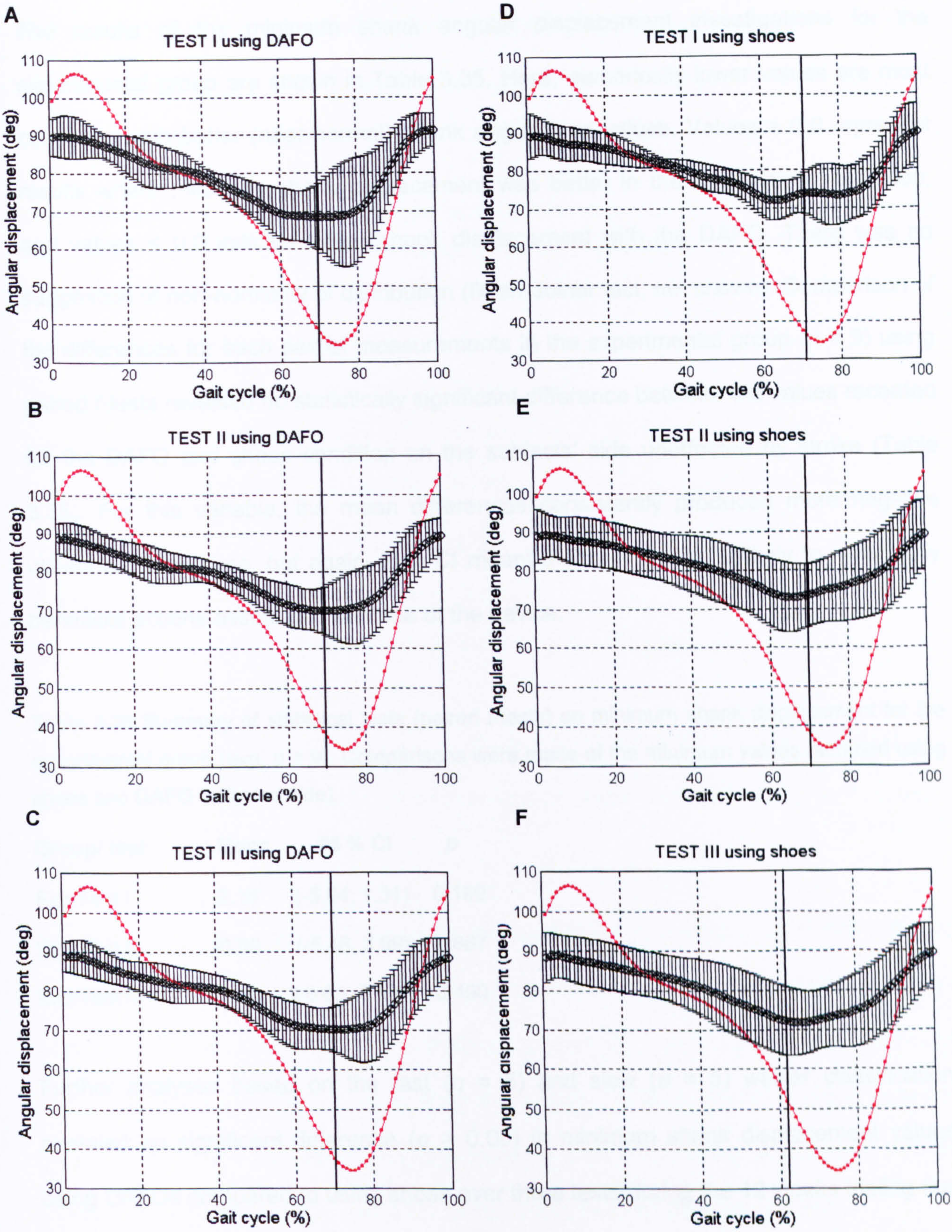


Figure 3.24 c Shank angular displacement of **slow** walkers: affected side

Values are shown using DAFO (A-C, n = 5) and using shoes (D-F, n = 4) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

The results of the minimum shank angular displacement investigations for the experimental group are shown in Table 3.35. Here, numerically lower values are most consistent with better (near normal) shank angulations values. Values > 0.0 represent results where minimum shank displacement was better in the shoes-alone condition, and values < 0.0 indicate better shank displacement with the DAFO. There was no suggestion of non-normality of distribution (Ryan-Joiner test, not shown). Comparison of the differences for each pair of measurements in the experimental group (n = 9) using paired t-tests revealed no statistically significant difference between the values recorded for the DAFO and shoes condition on the subjects' side unaffected by stroke (Table 3.35). For this variable, the mean differences consistently produced more negative values for DAFO use, but again, high CI meant that this seems unlikely to reflect any beneficial actions associated with use of the device.

Table 3.35 Summary of statistical tests (paired t-tests) on minimum shank displacement for the experimental group (exp, n = 9). Comparisons were made of the minimum values recorded using shoes and DAFO (affected side).

Group/ test	Mean	95 % CI	p
Exp/Test I	-2.16	(-5.64, 1.31)	0.189
Exp/Test II	-0.89	(-5.46, 3.69)	0.667
Exp/Test III	-1.64	(-6.85, 3.58)	0.490

Further analyses based on the fast (n = 5) and slow (n = 5) walker classification revealed no significant difference (p > 0.05) in minimum shank displacement values using DAFOs compared to using shoes over three tests during the 12 weeks testing trial (Table 3.36). It was noted that the mean values consistently yielded negative numbers over the three tests for the fast walkers, which is suggestive of better minimum shank displacement with DAFOs than with shoes. However, the CI of the group data revealed large variability between subjects and that some subjects displayed better minimum shank displacement with shoes than with DAFOs. Thus, potentially beneficial effects of

DAFOs on stroke patients' minimum shank displacement were only evident for six of the nine subjects over the testing period. Such effects are not apparent when data are considered on a group basis.

Table 3.36 Summary of statistical tests (paired *t*-tests) on minimum shank displacement for the experimental group data separated according to fast (n = 5) and slow (n = 4) walkers status (affected side).

Group/ Test	Mean	95 % CI	*p*
Fast/Test I	-1.062	(-3.362, 1.238)	0.269
Fast/Test II	-0.70	(-6.30, 4.90)	0.747
Fast/Test III	-1.25	(-5.00, 2.50)	0.407
Slow/Test I	-3.54	(-14.26, 7.18)	0.371
Slow/Test II	-1.12	(-14.16, 11.91)	0.802
Slow/Test III	-2.12	(-18.82, 14.58)	0.714

Differences between the minimum shank displacement values for the DAFO and shoe conditions on the side unaffected by stroke were not statistically different ($p < 0.05$, not shown).

For each group, the values recorded for the unaffected side were most consistent with nearer normal (more negative, $p < 0.05$) minimum shank displacement levels compared to the affected side, indicating asymmetrical gait. In the control group, the unaffected side shank data was 16.5 % lower than the affected side. In contrast, the unaffected side values for the experimental group were 38.7 % lower using shoes, and 31.3 % using DAFOs (fast walkers), and 42 % using shoes or DAFOs (slow walkers).

Minimum thigh displacement

Determination of subjects' thigh angular displacement was ascertained from coordinate data of the knee and hip markers and the measurements to estimate the angle of the thigh segment in space (the global reference frame) during the gait cycle. Although the

angle obtained was not the actual joint angle, it reflects angle changes at the hip joint (Wu, 1995a). The results of these investigations are presented in Figure 3.24. The mean thigh angular displacement of the healthy subjects (n = 4) demonstrated motion from 118° at heel strike to 77° during the push-off phase, when the hip joint is extended. Subsequently, the direction of thigh rotation increased, when the hip was flexed during swing phase. The minimum thigh angular displacement was achieved in the push-off (late stance) phase, when the hip joint was fully extended (Figure 3.25, red trace).

The thigh angular displacement data collected for the control group (Figure 3.25 a) and experimental group fast walkers (Figure 3.25 b) revealed a similar pattern to that obtained for the comparative healthy subject group. In contrast, the experimental group slow walkers (Figure 3.25 c) displayed a noticeably different pattern to that of the healthy subjects, with thigh motion remaining at low levels (< 20° between minimum and maximum angles) throughout the gait cycle.

The results of the minimum thigh angular displacement investigations for the experimental subjects were analysed using within-group data comparisons. Numerically lower values correspond to better thigh angulations; values > 0.0 are consistent with results where minimum thigh displacement was nearer normal with shoes, and values < 0.0 indicate nearer normal thigh displacement with the DAFO. Comparison of the differences for each pair of measurements in the experimental group (n = 9) using paired t-tests yielded no statistically significant differences between the values recorded for the DAFO and shoe conditions on the subjects' side unaffected by stroke (Table 3.37).

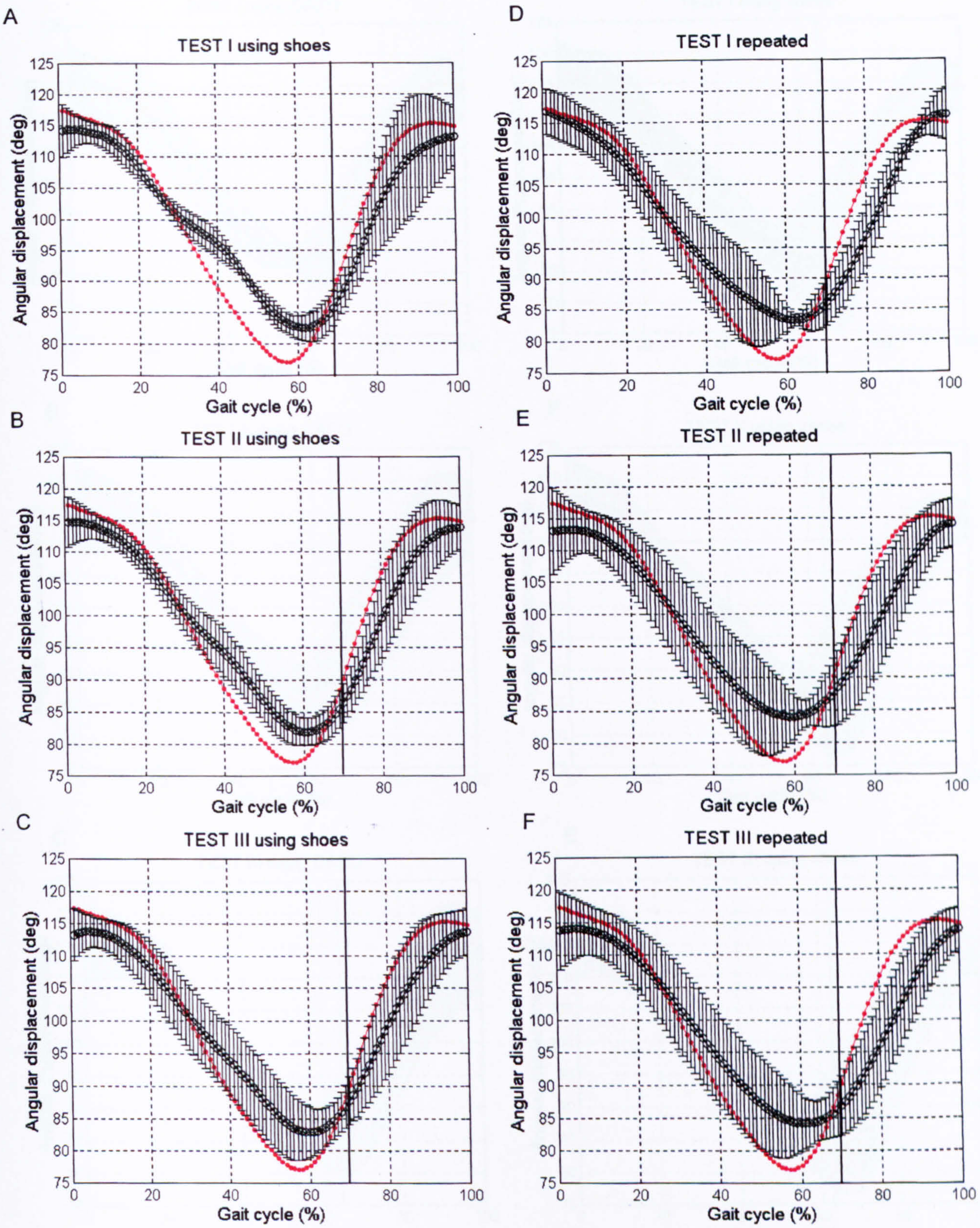


Figure 3.25 a Thigh angular displacement of control subjects (n = 3): affected side

Values are shown for trial I (A-C) and trial II (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

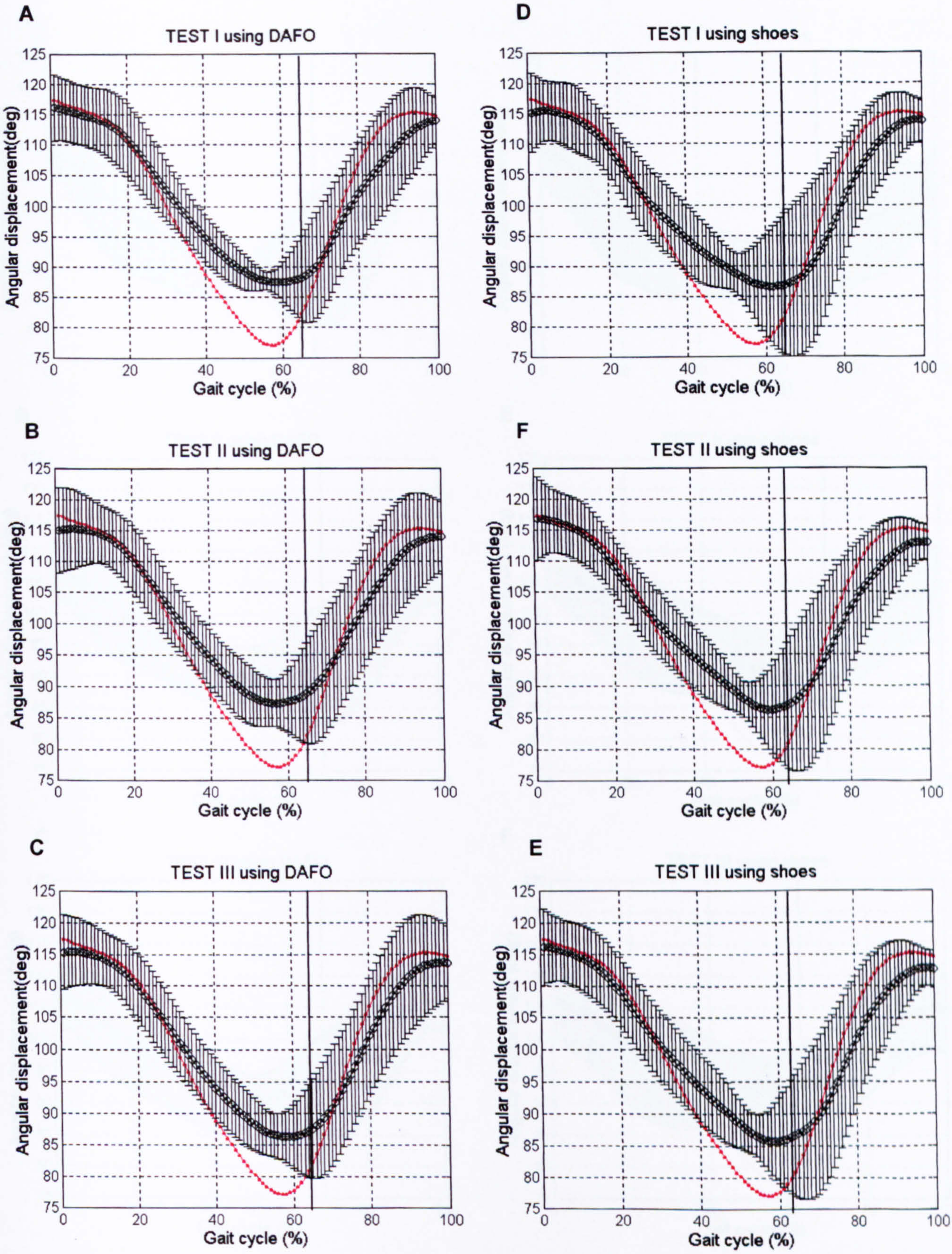


Figure 3.25 b Thigh angular displacement of **fast** walkers (n = 5): affected side

Values are shown using DAFO (A-C) and using shoes (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

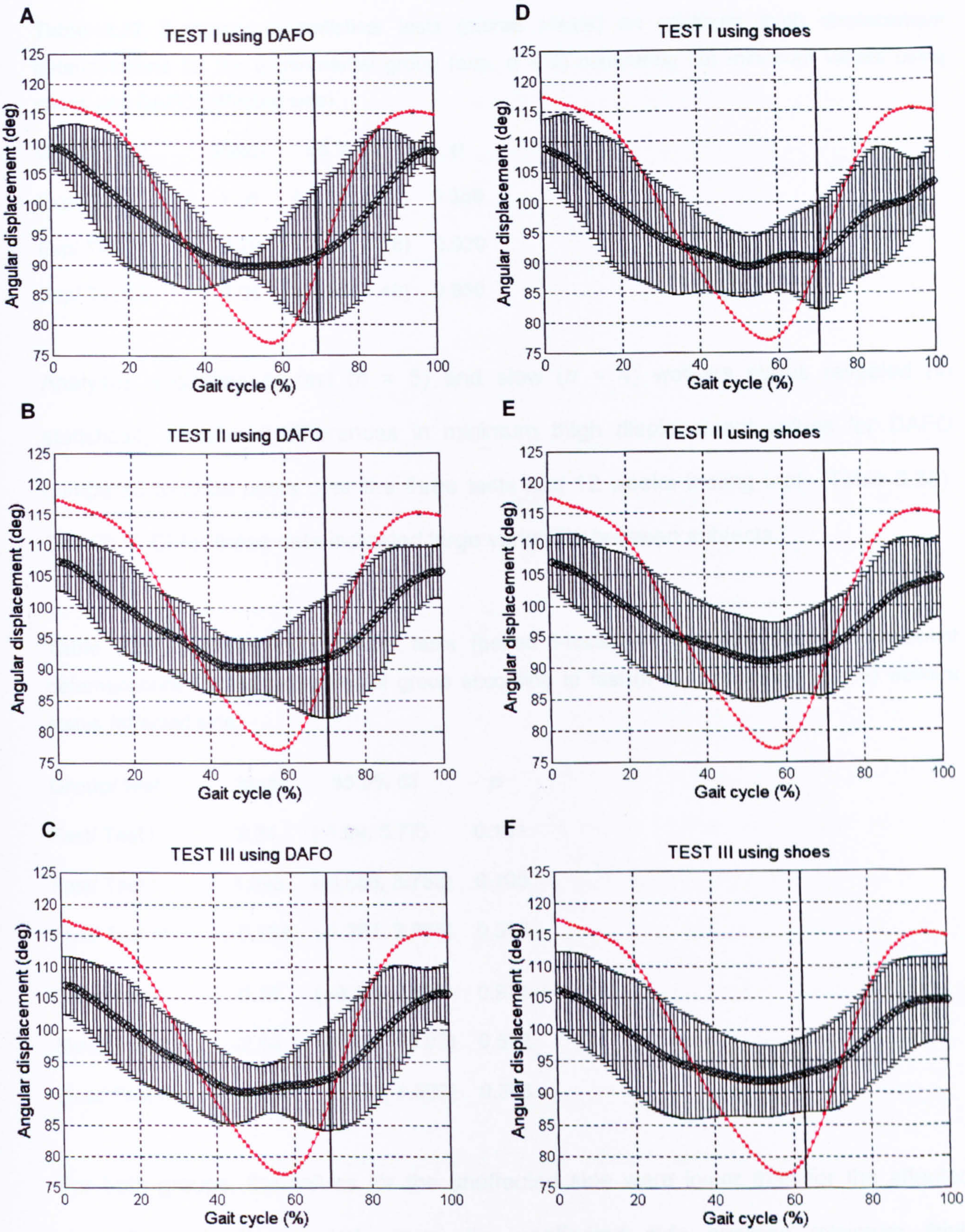


Figure 3.25 c Thigh angular displacement of **slow** walkers: affected side

Values are shown using DAFO (A-C, n = 5) and using shoes (D-F, n = 4) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

Table 3.37 Summary of statistical tests (paired *t*-tests) on minimum thigh displacement determinations for the experimental group (exp, *n* = 9) comparing the minimum values using shoes and DAFO (affected side).

Group/ test	Mean	95 % CI	*p*
Exp/ Test I	1.26	(-1.72, 4.24)	0.359
Exp/ Test II	-0.20	(-4.58, 4.18)	0.920
Exp/ Test III	0.04	(-1.38, 1.46)	0.950

Analyses according to fast (*n* = 5) and slow (*n* = 4) walkers status revealed no statistically significant differences in minimum thigh displacement values for DAFO compared to shoe users over the three tests and 12 weeks testing trial (Table 3.38). The 95 % CI for these data indicated large variability between subjects.

Table 3.38 Summary of statistical tests (paired *t*-tests) on minimum thigh displacement determinations for the experimental group according to fast (*n* = 5) and slow (*n* = 4) walkers status (affected side).

Group/ test	Mean	95.0% CI	*p*
Fast/ Test I	2.34	(-1.09, 5.77)	0.131
Fast/ Test II	1.598	(-0.556, 3.752)	0.108
Fast/ Test III	0.784	(-1.297, 2.865)	0.355
Slow/ Test I	-0.10	(-8.13, 7.93)	0.971
Slow/ Test II	-2.44	(-15.80, 10.92)	0.602
Slow/ Test III	-0.890	(-3.773, 1.993)	0.398

For both groups, the values for the unaffected side were lower than for the affected side. Thus, in the control group, the unaffected side average minimum thigh displacement value over the three tests were 3.2 % better (minimum values nearer normal) than the affected group. In the experimental group fast walkers, the unaffected side values were 6.8 % (shoes) and 6.5 % (DAFO) better compared to the side affected by stroke. The corresponding values for the slow walkers were 4.2 % (shoes) and 5.1 % (DAFOs).

Segmental angular velocity

Further assessments of the effects of DAFOs on lower limb function during the gait cycle involved studies of segmental angular velocity. Subjects' gait was assessed by analysing angular velocities of the foot, shank and thigh segments, during two strides, in the sagittal plane, and for the affected and (simultaneously) unaffected leg (section 2.6.5).

The foot angular velocity (degrees/sec) estimates the rate of change of foot angular displacement with respect to time. The comparative data for the foot angular velocity of healthy subjects (Figure 3.26, red traces) illustrate representative velocity curves for a full gait cycle. These data show how the velocity initially decreases to zero from the heel strike to the foot flat position, and then remains fairly constant in mid stance phase, when there is no angular displacement (Enoka, 2002). When the push off phase begins (heel rise), the velocity becomes negative, exhibiting a large negative velocity spike at the end of the push off and early swing phase, as the foot is lifted from the floor (ankle fully extended). During swing phase the velocity curve passes zero again, when the direction of the movement changes from plantarflexion (extension) to dorsiflexion (Enoka, 2002). Finally, the foot velocity data display a large positive spike during swing phase, achieving their maximum value in mid swing phase (ankle maximally flexed) when the velocity starts to decrease, slowing down for the next heel strike. In these graphs (Figures 3.26) positive velocity indicates that the ankle joint is flexing (dorsiflexion), and negative velocities that it is extending (plantarflexion).

Of primary interest are the minimum (the end of stance phase and early swing phase) and maximum (the middle of swing phase) values, which provide indices of velocity changes, whilst at the same time indicating the direction of the movement changes in the gait cycle. In this study, the healthy subject data (n = 4) revealed a mean minimum value of - 405 °/sec and a mean maximum of 496 °/sec. It can be seen from Figure 3.26 b - c that the foot velocity data of the control and experimental groups followed a similar

pattern to that of the healthy subjects, although the slow walkers displayed minimal negative-spiking before early swing phase (due to limited ankle plantar-flexion).

Minimum foot velocity

With the stroke subjects, the minimum foot angular velocity values that are more negative correspond to better (more normal) foot velocity. In the control group (n = 3), on the affected side, the mean minimum foot velocity was 32.1 % more negative than that of the experimental fast walkers (n = 5) using shoes, and 11.3 % using DAFOs (Figure 3.26 a - b). The experimental group slow walkers' (n = 5) minimum values were markedly less negative than those of the control group, with a difference of 169 % evident with shoes and 254 % with DAFOs (Figure 3.26 a and c).

Within-experimental-group data analyses were undertaken as described earlier. Thus, data obtained for the three tests were considered in relation to the individual differences of DAFO (D) minus shoe (S) minimum foot angular velocity values for each subject, denoted as D1-S1, D2-S2 and D3-S3. Here, values > 0.0 define results where minimum foot velocity was better (nearer normal) when shoes were used, and values < 0.0 indicate better foot displacement when a DAFO was used. Here, the data were found to be normally distributed in test I and test III, but not in test II (Ryan-Joiner test, not shown). Statistical analyses of the differences were done for each pair of measurements within the experimental group (n = 9; data for one subject was unavailable because she was not confident to walk without the DAFO). Both parametric (paired t-tests) and non-parametric (Wilcoxon signed rank test) comparisons failed to identify statistically significant differences between the values recorded for the DAFO and shoes condition on the subjects' side affected by stroke (Table 3.39). The CI for these data indicated substantial variability between subjects. This may be due to the limited number of subjects, or/and, the calculation used to determine the angular velocity (Winter, 1990), which may have exaggerated the error of the measurements (see accuracy tests in section 2.5.3).

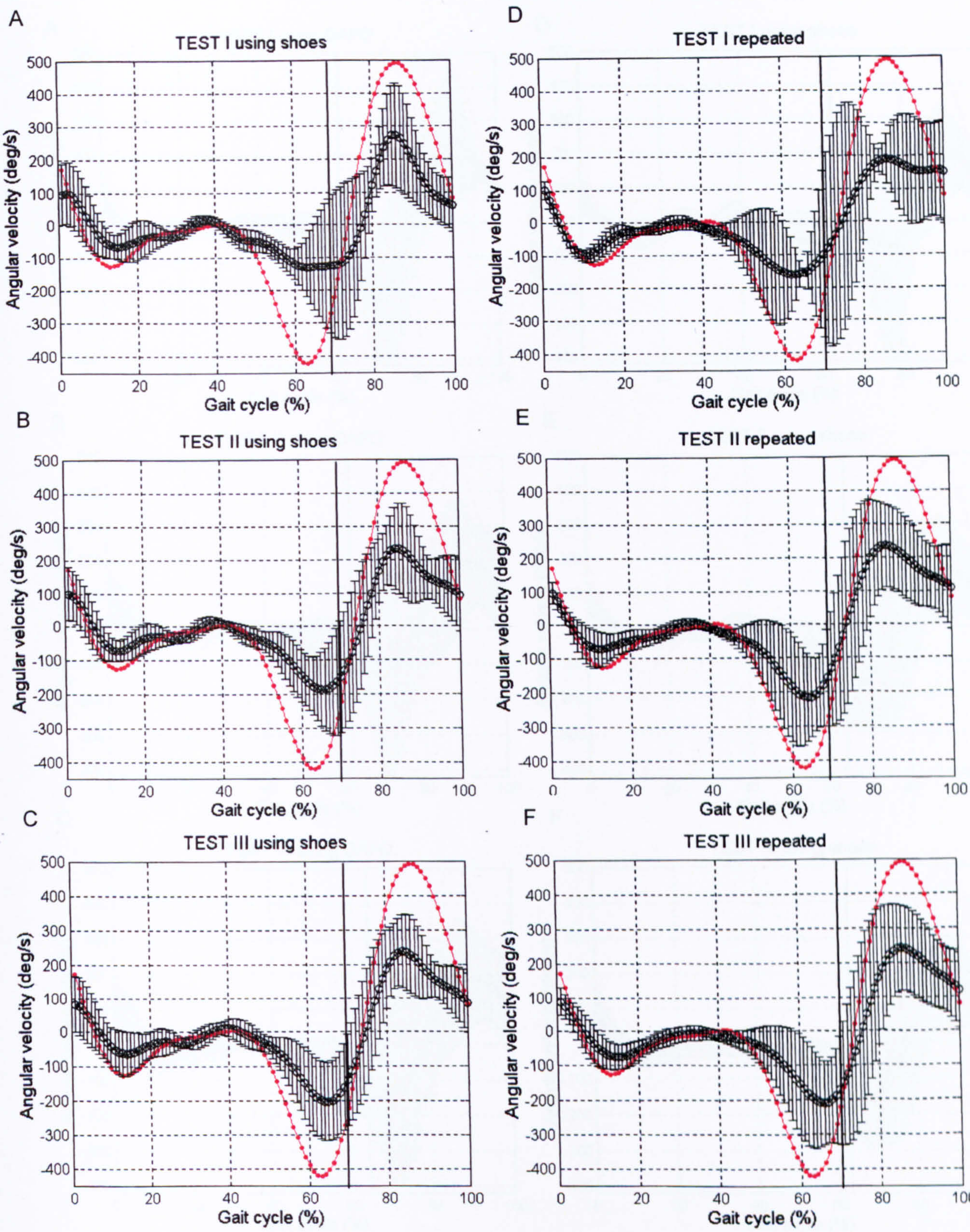


Figure 3.26 a Foot angular velocity of control subjects (n = 3): affected side

Values are shown for trial I (A-C) and trial II (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

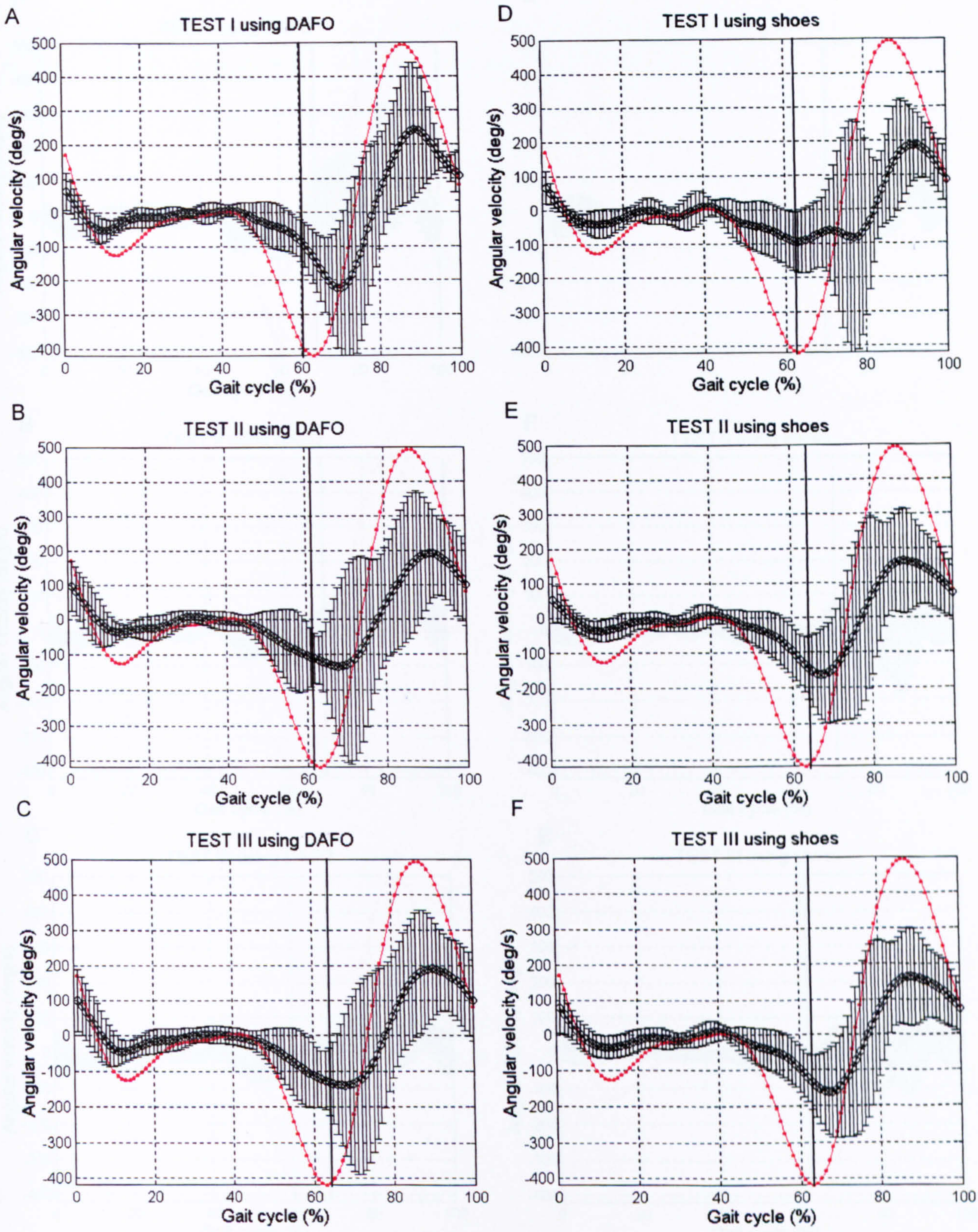


Figure 3.26 b Foot angular velocity of **fast** walkers (n = 5): affected side

Values are shown using DAFO I (A-C) and using shoes (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

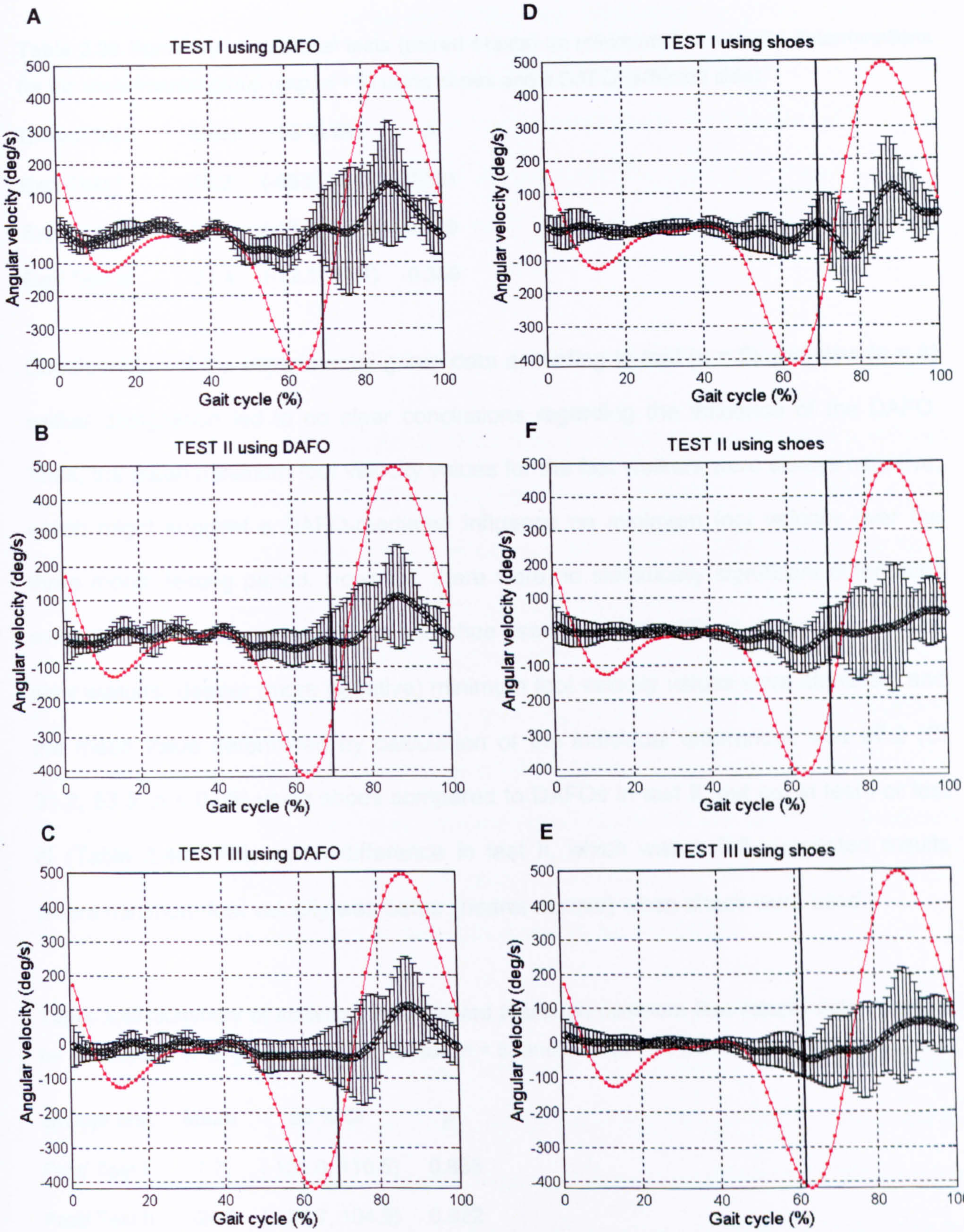


Figure 3.26 c Foot angular velocity of **slow** walkers: affected side

Values are shown using DAFO (A-C, $n = 5$) and using shoes (D-F, $n = 4$) and are the mean $\pm$ SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

Table 3.39 Summary of statistical tests (paired *t*-tests) on minimum foot velocity determinations for the experimental group (exp, *n* = 9) using shoes and a DAFO (affected side).

Group/ test	Mean	95 % CI	*p*
Exp/ Test I	-13.2	(-65.9, 39.6)	0.581
Exp/ Test II	29.4	(-48.5, 107.2)	0.409
Exp/ Test III	-21.4	(-72.1, 29.4)	0.359

Consideration of the experimental group data according to fast (*n* = 5) and slow (*n* = 4) walker designation led to no clear conclusions regarding the influence of the DAFO. Thus, the mean minimum foot velocity values for the fast walkers were always negative, which might suggest a DAFO-mediated influence on minimum foot velocity over the three month testing period. However, there were no statistically significant differences evident between values for DAFOs and shoe users with fast walkers. In addition, for the slow walkers, deeper (more negative) minimum foot velocity values were identified, and the mean value determined by calculation of the individual differences was 97.2 (CI 31.2, 63.3, $p < 0.05$) using shoes compared to DAFOs in test II, but not in test I or test III (Table 3.40). This mean difference in test II, which was > 0.0 suggested results where minimum foot velocity was better (nearer normal) when shoes were used.

Table 3.40 Summary of statistical tests (paired *t*-tests on minimum foot velocity determinations for the experimental group according to fast (*n* = 5) and slow (*n* = 4) walker status (affected side).

Group/ test	Mean	95 % CI	*p*
Fast/ Test I	-7.7	(-126.0, 110.5)	0.865
Fast/ Test II	-24.9	(-154.7, 104.9)	0.622
Fast/ Test III	-51.1	(-147.3, 45.1)	0.214
Slow/ Test I	-19.92	(-50.39, 10.56)	0.129
Slow/ Test II	97.2	(31.2, 63.3)	0.018*
Slow/ Test III	15.74	(-12.29, 43.76)	0.172

* $p < 0.05$

For both groups, the values obtained for the side unaffected by stroke were more favourable than to those for the affected side. Thus, in the control group the unaffected side values were 40 % more negative than those obtained for the affected side. In the experimental group, the unaffected side values were 122.9 % lower with shoes and 56.8 % lower with DAFOs (fast walkers), and 88 % using shoes and 272 % using DAFO (slow walkers).

Maximum foot velocity

In the control group (n = 3), on the affected side, the average maximum foot velocity over the three tests was 36.2 % higher compared to the fast walkers (n = 5) using shoes and 12.4 % using DAFOs. The experimental group slow walkers' maximum values were noticeably slower than those of the control group, with differences of 194.4 % and 99.1 % using shoes (n = 4) and DAFOs (n = 5), respectively. In the experimental group, the fast walkers maximum values recorded wearing shoes were 116 % higher compared to those determined for the slow walkers and 76.3 % higher for the DAFO condition. On the unaffected side, the differences between mean values for the control subjects and experimental fast walkers were small, whereas comparisons with the slow walkers revealed clear differences of 53 % with shoes and 43 % with DAFOs.

Within-group data analyses of the experimental group (n = 10) were also undertaken as described earlier; comparisons were made of the differences for each paired measurements. There was no evidence of non-normality of distribution (Ryan-Joiner test, not shown). Paired t-tests revealed a statistically significant difference between the values recorded for the DAFO and shoes conditions on the subjects' side affected by stroke in test I (p = 0.036), but not in test II and test III (Table 3.41). The difference identified in test I, which was > 0.0, suggests results where maximum foot velocity was better (nearer normal) when DAFOs were used. In the later tests, the CI indicate substantial variability between subjects which, perhaps, may also be indicative of

learning effects associated with use of the DAFO, or/and limitations imposed by the number of subjects used for these experiments.

Table 3.41 Summary of statistical tests (paired *t*-tests) on maximum foot velocity determinations within the experimental group (exp, n = 9) comparing the maximum values using shoes and DAFOs (affected side).

Group/ test	**Mean**	**95 % CI**	***p***
Exp/ Test I	62.6	(5.2, 120.0)	0.036*
Exp/ Test II	-9.0	(-74.0, 55.9)	0.756
Exp/ Test III	39.4	(-27.4, 106.2)	0.211

* $p < 0.05$

Further analyses based on the fast (n = 5) and slow (n = 4) walker classification revealed no significant differences ($p > 0.05$) between maximum foot velocity values using shoes compared to DAFOs (Table 3.42). Consistently positive mean values for the fast walkers and predominantly positive for the slow walkers suggested that, in these tests, maximum foot velocities were higher using DAFOs compared the shoes alone ($p > 0.05$).

Table 3.42 Summary of statistical tests (paired *t*-tests) on maximum foot velocity determinations within the experimental group according to fast (n = 5) and slow (n = 4) walkers status (affected side).

Group/ test	**Mean**	**95 % CI**	***p***
Fast/ Test I	77.3	(-1.6, 156.3)	0.053
Fast/ Test II	24.0	(-93.9, 141.9)	0.602
Fast/ Test III	49.8	(-87.0, 186.6)	0.369
Slow/ Test I	44.2	(-104.0, 192.3)	0.413
Slow/ Test II	-50.3	(-136.0, 35.4)	0.158
Slow/ Test III	26.4	(-68.2, 120.9)	0.440

In both groups, the values obtained for the unaffected side were nearer normal than for the affected side. In the control group, the values determined for the unaffected side were 62.8 % higher than those of the affected side. In the experimental group, the unaffected side values were 69.8 % higher using shoes and 53.7 % using DAFO (fast walkers), and 173.9 % using shoes and 97.6 % using DAFOs (slow walkers).

Shank velocity

Data for the angular velocity of the shank provide information on the rate of change of shank angular displacement with respect to time throughout a full gait cycle (section 2.6.5). Despite the angle obtained not being the actual joint angle, it reflects angular changes at the knee joint flexion-extension (Winter, 1990; Roberts *et al.*, 1997; Wooley, 2001). The graphed data for the comparative database of healthy subjects (n = 4) illustrate the sequence of events involving this variable in a typical gait cycle (Figure 3.27, red traces). Initially, the shank rotational velocity in the saggital plane decreased from the heel strike to the foot flat position, when the knee is partially flexed. During the mid stance phase, the velocity of the shank increased to zero level, and then reverted to negative values during the push-off phase (heel rise). Deep negative velocity spikes were achieved towards the end of the push-off in early swing phase, when the foot was raised off the ground. Shank velocity displayed strongly positive spiking during the swing phase, and achieved maximum levels in the mid swing phase, where it began to decrease in preparation for the next stance phase. Consequently, for the healthy subjects, the critical points were the minimum (-198 °/sec) and maximum (395 °/sec) angular velocity values.

Minimum shank velocity

Shank angular velocity of the control (n = 3, Figure 3.27 a) and experimental, (fast walkers, n = 5 and slow walkers, n = 5, Figure 3.27 b - c) groups followed a similar pattern to that of the comparative healthy subject data, although the experimental slow

walkers displayed negligible negative spiking throughout the heel strike and push-off phases. In the control group, on the affected side, the average minimum shank velocity was 70.4 % more negative compared to that of the fast walkers using shoes, and 56.5 % more negative using DAFO. In the experimental group slow walkers, the minimum values were much less negative than for the control group; 270 % less negative with shoes and 250 % less negative with DAFOs.

Within-experimental-group data analyses were undertaken as described earlier. Data obtained were considered in relation to the individual difference of DAFO (D) minus shoe (S) minimum shank angular velocity values for each subject. Here, values > 0.0 define results where minimum shank velocity was better (nearer normal) when shoes were used, and values < 0.0 indicate better shank velocity when a DAFO was used. In this case, paired *t*-tests failed to identify statistically significant differences between the values recorded for the DAFO and shoes condition on the subjects' side unaffected by stroke (Table 3.43). The mean difference values were predominantly negative (suggesting potentially nearer normal values with the DAFO than with shoe use) but the CI for the grouped data indicated large variation between subjects.

Table 3.43 Summary of statistical tests (paired *t*-tests) on minimum shank velocity determinations for the experimental group (exp, $n = 9$) using shoes and a DAFO (affected side).

Group/ test	**Mean**	**95.0% CI**	***p***
Exp/ Test I	-3.70	(-17.14, 9.74)	0.544
Exp/ Test II	-4.31	(-22.80, 14.19)	0.606
Exp/ Test III	-21.4	(-59.2, 16.4)	0.228

The subsequent analyses based on the fast ($n = 5$) and slow ($n = 5$) walker classification revealed no significant differences ($p > 0.05$) in minimum shank velocity values using DAFOs compared to using shoes over the three tests during the 12 weeks testing trial (Table 3.44).

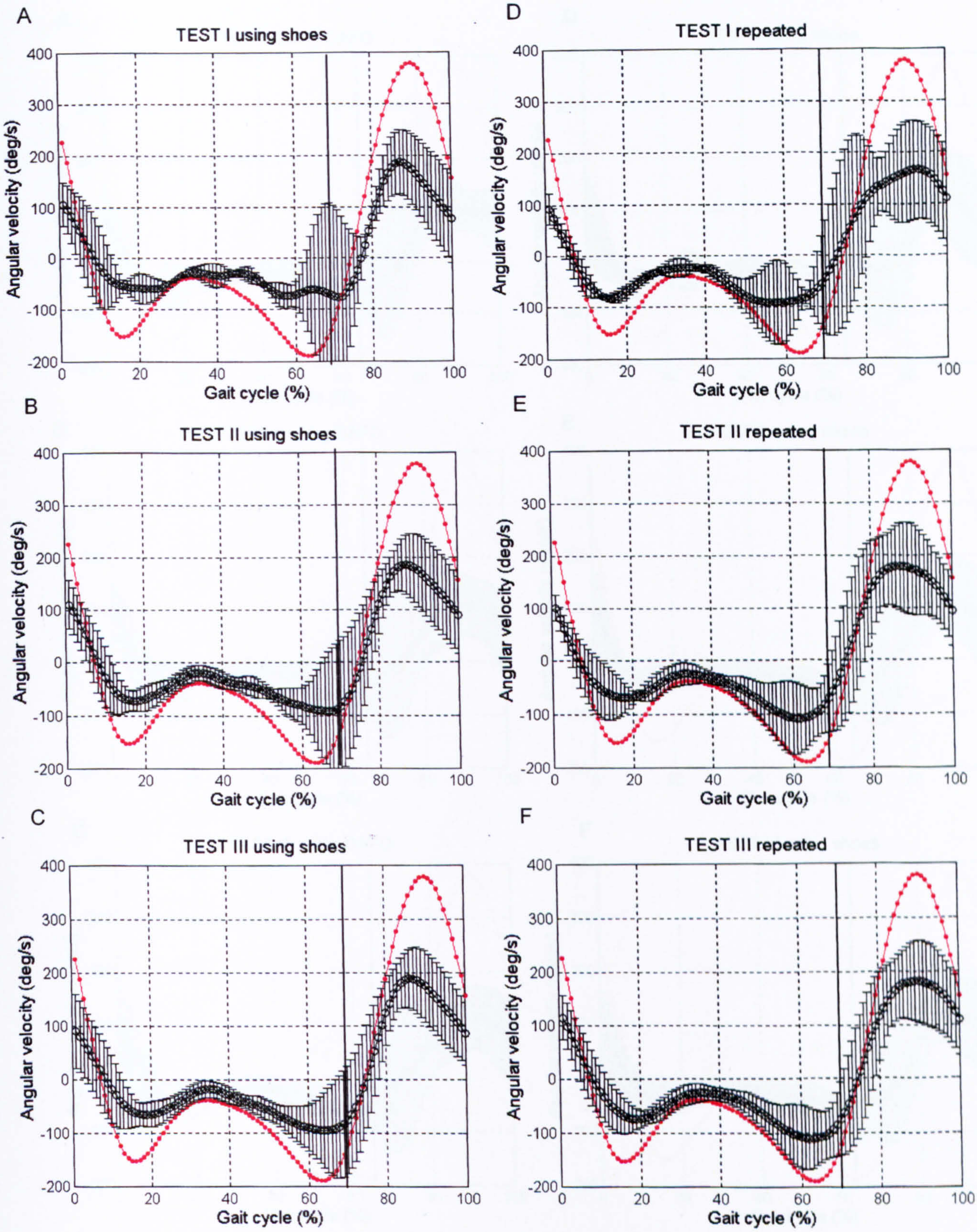


Figure 3.27 a Shank angular velocity of control subjects (n = 3): affected side

Values are shown for trial I (A-C) and trial II (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

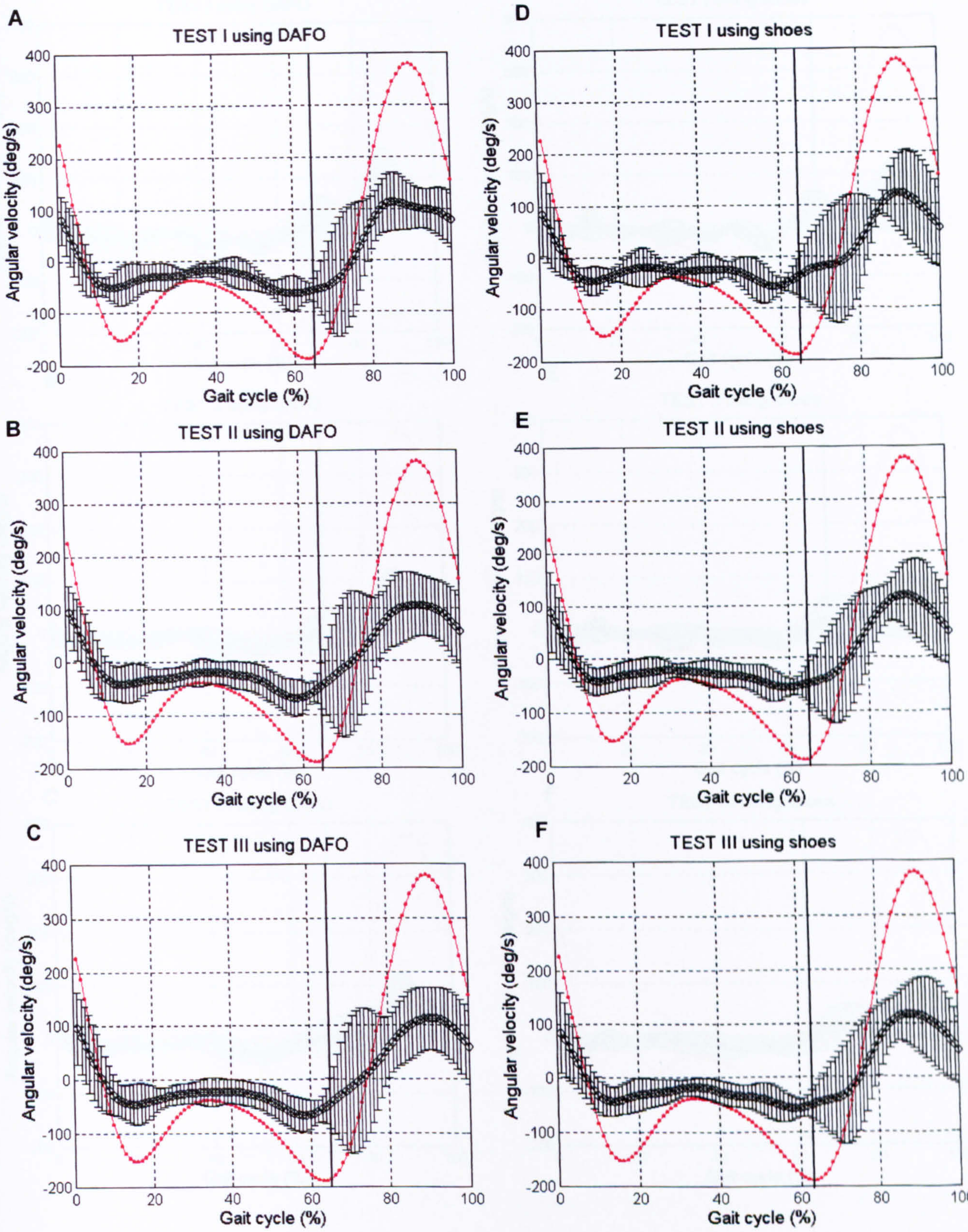


Figure 3.27 b Shank angular velocity of **fast** walkers (n = 5): affected side

Values are shown using DAFO (A-C) and using shoes (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the black line separates stance (left of line) and swing (right of line) phases.

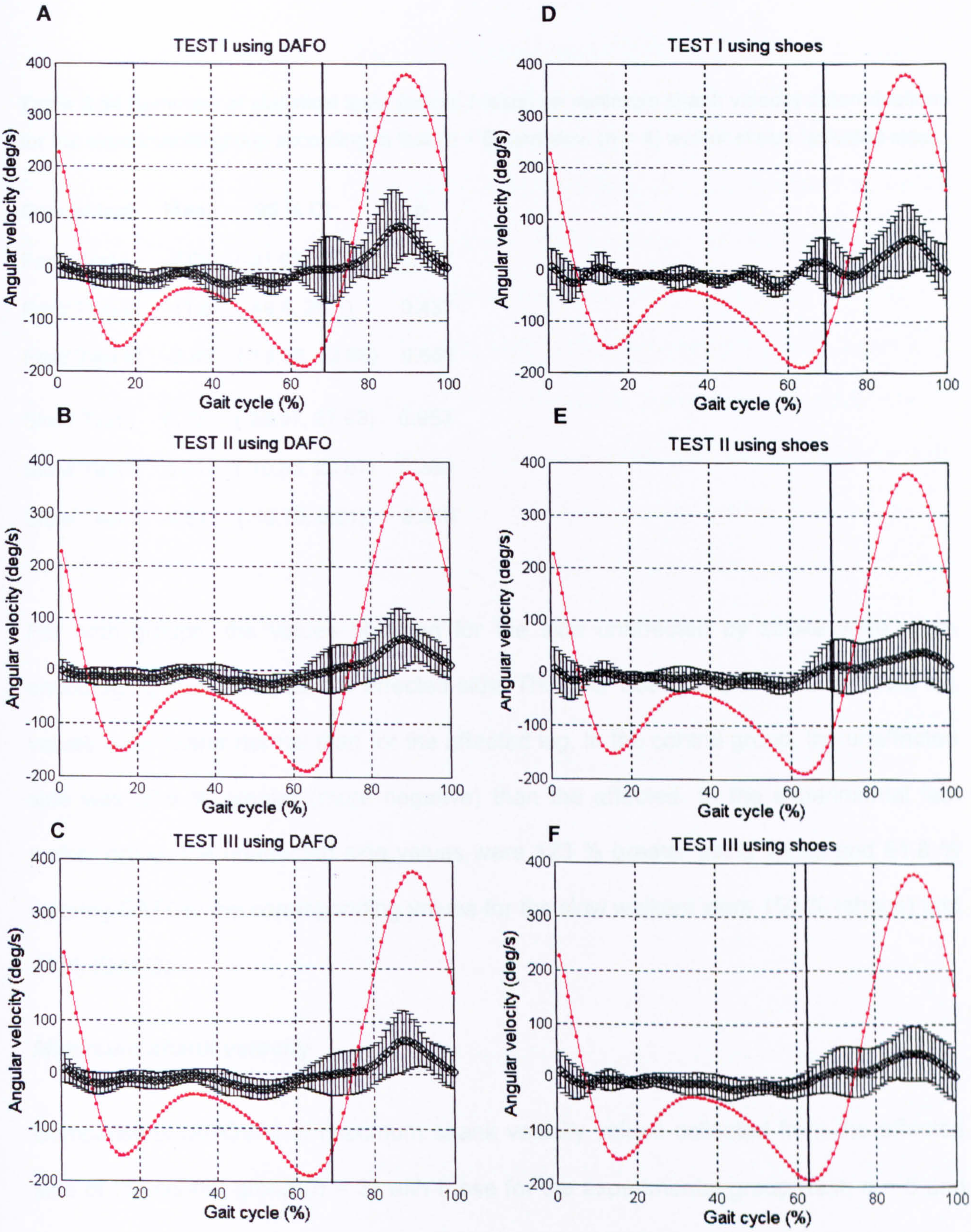


Figure 3.27 c Shank angular velocity of **slow** walkers: affected side

Values are shown using DAFO (A-C, $n = 5$) and using shoes (D-F, $n = 4$) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the black line separates stance (left of line) and swing (right of line) phases.

Table 3.44 Summary of statistical tests (paired *t*-tests) on minimum shank velocity determinations for the experimental group according to fast (n = 5) and slow (n = 4) walker status (affected side).

Group/ test	Mean	95 % CI	*p*
Fast/ Test I	-7.08	(-31.01, 16.85)	0.457
Fast/ Test II	-11.8	(-49.6, 26.1)	0.437
Fast/ Test III	-2.86	(-19.38, 13.66)	0.656
Slow/ Test I	0.53	(-25.97, 27.03)	0.953
Slow/ Test II	5.01	(-10.85, 20.87)	0.389
Slow/ Test III	-6.59	(-19.79, 6.61)	0.210

For both groups, the values obtained for the side unaffected by stroke were more encouraging than those for the affected side. Thus, for both groups, the unaffected leg values were nearer normal than for the affected leg. In the control group, the unaffected side was 20.6 % greater (more negative) than the affected. In the experimental fast walker group, the unaffected side values were 123 % greater using shoes and 61.8 % wearing DAFOs; the corresponding values for the slow walkers were 150 % (shoes) and 91 % (DAFOs).

Maximum shank velocity

Comparisons (ANOVA) of maximum shank velocity values collected from the affected side of the control group (n = 3) with those for the experimental group (fast, n = 5 and slow, n = 4 walkers) revealed a statistically significant difference ($p < 0.05$) with higher (nearer normal) maximum shank values for the control group. Thus, for the control group, on the affected side, maximum shank velocity values were, on average, 51.5 % higher compared to those recorded for the fast walkers using shoes, and 64.4 % higher using DAFOs. For the experimental group slow walkers, the maximum values were

clearly lower than the control group, with differences of 266 % with shoes and 157 % with DAFOs.

Further within-group analyses of the experimental subjects (n = 10) as described earlier were undertaken. Here, values < 0.0 suggest results where maximum shank velocity was better (nearer normal) when shoes were used, and values > 0.0 imply better shank velocity when a DAFO was used. The data were distributed normally (Ryan-Joiner test, not shown) and statistical analyses of the differences were done for each pair of measurements within the experimental group using shoes and DAFO. Paired t-tests failed to identify statistically significant differences between the values recorded for the DAFO and shoes condition on the subjects' side unaffected by stroke (Table 3.45). The CI for these data indicated substantial variability between subjects over the three tests.

Table 3.45 Summary of statistical tests (paired t-tests) on maximum shank velocity determinations for the experimental group (exp, n = 9) using shoes and a DAFO (affected side).

Group/ test	Mean	95 % CI	p
Exp/ Test I	0.3	(-28.3, 28.8)	0.983
Exp/ Test II	-6.27	(-26.50, 13.96)	0.495
Exp/ Test III	0.3	(-28.3, 28.8)	0.983

Analyses based on the fast (n = 5) and slow (n = 4) walker classification revealed no significant difference (p > 0.05) in maximum foot displacement values using DAFOs compared to using shoes over the three tests during the 12 weeks testing trial (Table 3.46).

Table 3.46 Summary of statistical tests (paired *t*-tests) on maximum shank velocity determinations for the experimental group according to fast (n = 5) and slow (n = 4) walkers' status (affected side).

Group/ test	Mean	95 % CI	*p*
Fast/ Test I	-12.8	(-54.8, 29.2)	0.446
Fast/ Test II	5.6	(-30.3, 41.4)	0.688
Fast/ Test III	-12.8	(-54.8, 29.2)	0.446
Slow/ Test I	16.6	(-45.3, 78.5)	0.456
Slow/ Test II	-21.10	(-44.12, 1.92)	0.062
Slow/ Test III	16.6	(-45.3, 78.5)	0.456

On the unaffected side, only minor differences were seen between the control subjects and the experimental group fast walkers, whereas much larger differences were evident from comparisons with the experimental group slow walkers (57.9 % with shoes and 50.4 % with DAFOs). It was also found that, in each group, the unaffected side values were nearer normal than those of the affected side. In the control group, the mean maximum shank velocity was 51 % higher on the unaffected side compared to the affected. In the experimental group, for the fast walkers, the corresponding values were 113.5 % higher using shoes and 110.7 % wearing DAFOs. The corresponding values calculated for the slow walkers were 229 % (shoes) and 143 % (DAFOs).

Thigh velocity

Data for the angular velocity of the thigh enabled determination of the change in angular position of the thigh segment with respect to time within the global coordinates system (section 2.6.5). The angle obtained was not the actual joint angle, but is known to mirror angle changes of the hip joint (flexion-extension) movements (Winter, 1990; Roberts *et al.*, 1997; Wooley, 2001).

The graphical profile of the thigh segment velocity data for the comparative healthy subjects (n = 4) shows the sequence of events in relation to this variable during a typical gait cycle (Figure 3.28, red traces). Initially, the velocity in the saggital plane decreases from the heel strike to the foot flat position, when weight bears through the standing leg, with decreased velocity of the hip during joint extension controlling standing balance. After the mid stance phase, the velocity of the thigh increases, when the hip joint extension strongly increases using muscle power to help the push-off phase (heel rise). The high positive velocity spike occurring just before mid-swing phase represents the maximum hip flexion achieved, following which it decrease in preparation for the next heel strike. As was seen for other variables, it was found that the stroke (control and experimental fast walkers) thigh velocity data followed a similar pattern to that of the healthy subjects (Figure 3.28 a and b). Once again, the slow walkers' thigh velocity revealed a clearly different pattern, (Figure 3.28 c) with negligible spiking throughout stance phase.

The minimum value of thigh velocity occurred during mid stance phase, which is associated with the level of stability of the more proximal joints. The maximum thigh velocity was measured during early swing phase, which is associated with large ankle plantarflexion and knee extension (Lehmann *et al.*, 1987; De Quervain *et al.*, 1996; Olney and Richards, 1996). Consequently, for the healthy subjects, these peak velocity values of thigh motions (-118 °/sec minimum and 173 °/sec maximum) are critical points for identifying changes in the gait cycle (Figure 3.27, red traces).

Minimum thigh velocity

In the control group (n = 3), on the affected side, the mean minimum velocity determined was 19.2 % more negative compared to that of the experimental fast walkers (n = 5) using shoes, and 21.6 % more negative using DAFOs. In the experimental group, slow walkers (n = 4), the minimum values were clearly less

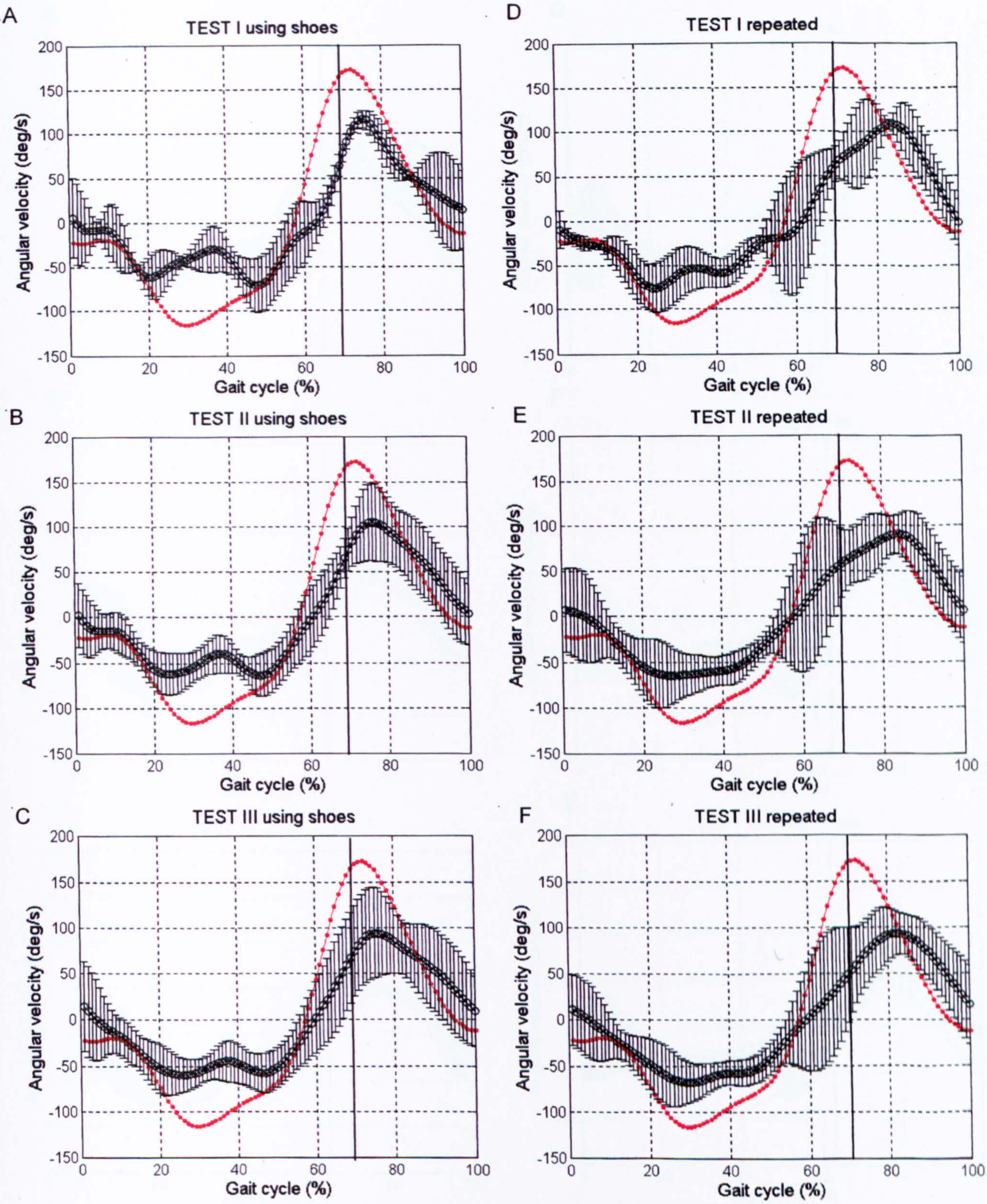


Figure 3.28 a Thigh angular velocity of control subjects (n = 3): affected side

Values are shown for trial I (A-C) and trial II (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

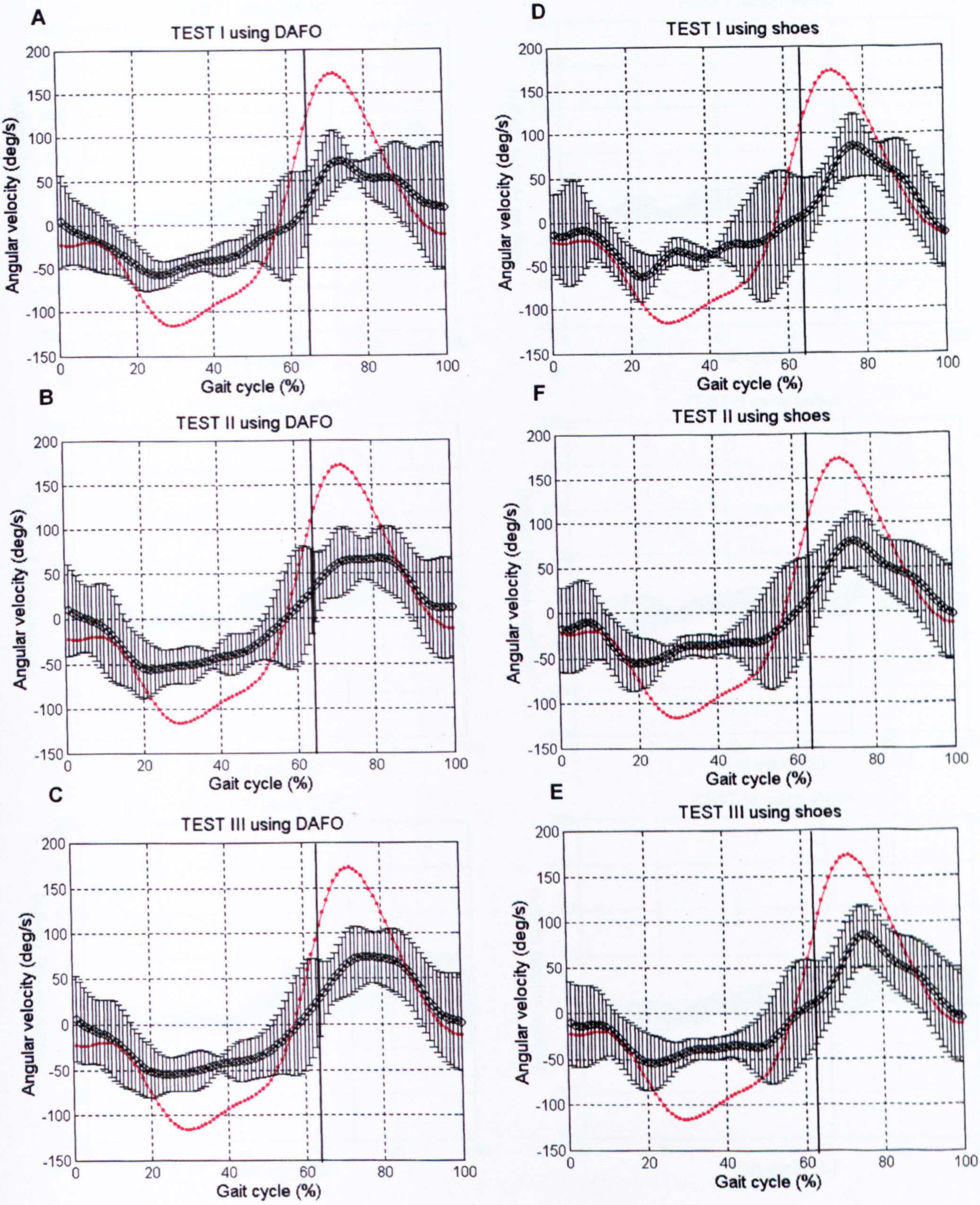


Figure 3.28 b Thigh angular velocity of **fast** walkers (n = 5): affected side

Values are shown using DAFO (A-C) and using shoes (D-F) and are the mean ± SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

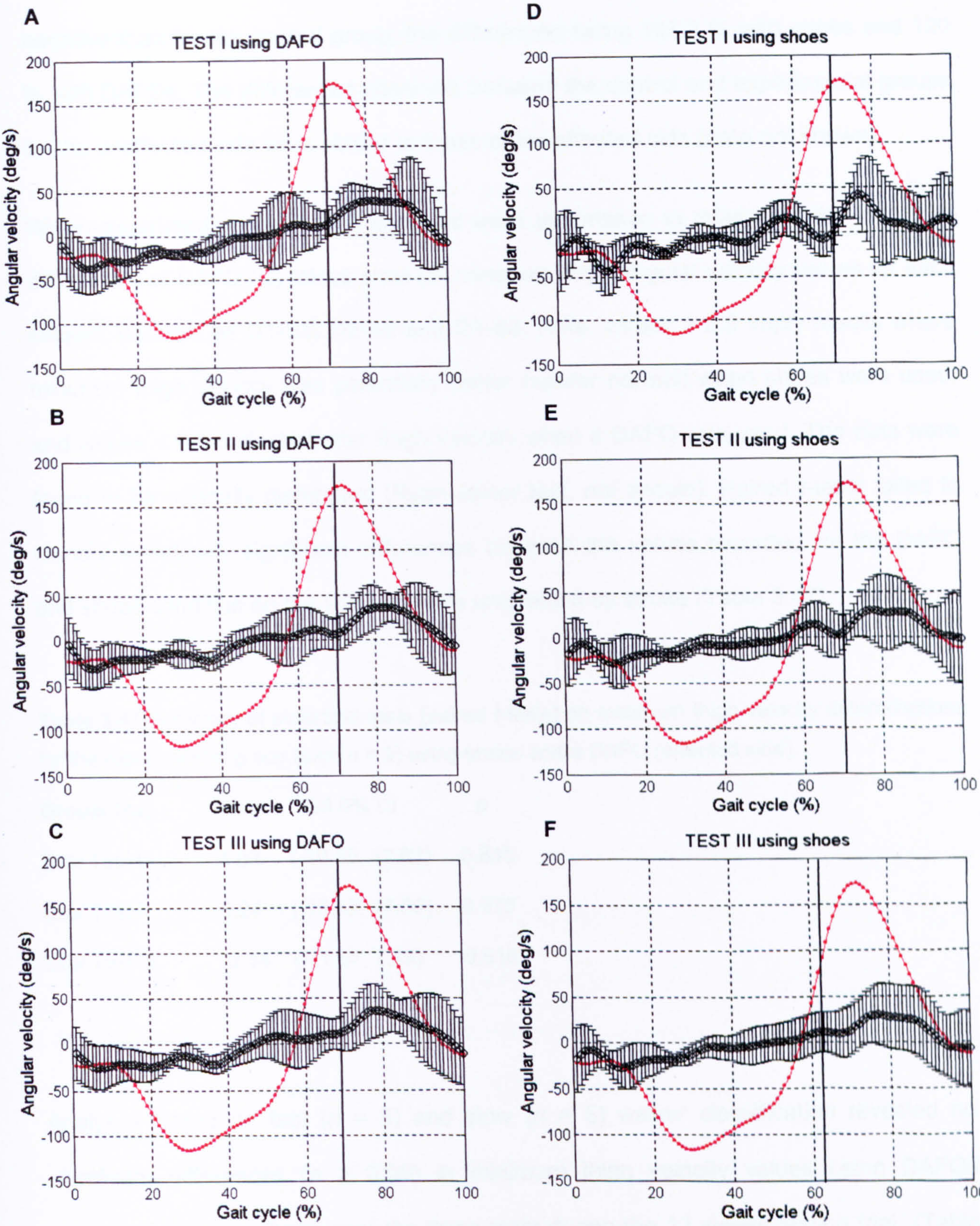


Figure 3.28 c Thigh angular velocity of **slow** walkers: affected side

Values are shown using DAFO (A-C, $n = 5$) and using shoes (D-F, $n = 4$) and are the mean $\pm$ SD of three separate tests as described in Methods. For comparative purposes, data collected using healthy subjects are given (red trace), where a typical swing phase would commence at 60% completion of the gait cycle (not marked). In each of the figures, the solid black line separates stance (left of line) and swing (right of line) phases.

negative than for the control group, the differences being 107.3 % with shoes and 120 % with DAFOs. The differences observed between the control and experimental groups on the unaffected side were similar to those of the affected side (data not shown).

Within-experimental-group data analyses were undertaken in relation to the individual differences of DAFO (D) minus shoe (S) minimum thigh angular velocity values for each subject, denoted as D1-S1, D2-S2 and D3-S3. Here, values > 0.0 imply results where minimum thigh velocity was potentially better (nearer normal) when shoes were used, and values < 0.0 indicate better thigh velocity when a DAFO was used. The data were found to be normally distributed (Ryan-Joiner test, not shown). Paired *t*-tests failed to identify statistically significant differences between the values recorded for the DAFO and shoes condition on the subjects' side unaffected by stroke (Table 3.47).

Table 3.47 Summary of statistical tests (paired *t*-tests) on minimum thigh velocity determinations for the experimental group (exp, $n = 9$) using shoes and a DAFO (affected side).

Group/ test	Mean	95.0% CI	*p*
Exp/ Test I	1.02	(-10.59, 12.62)	0.845
Exp/ Test II	0.24	(-15.52, 16.00)	0.973
Exp/ Test III	-2.14	(-11.57, 7.29)	0.615

Analyses based on fast ($n = 5$) and slow ($n = 5$) walker classification revealed no significant differences ($p > 0.05$) in minimum thigh velocity values using DAFOs compared to using shoes over the three tests during the 12 weeks testing trial (Table 3.48).

In each group, the values recorded for the unaffected side were nearer normal than those for the affected side. Thus, in the control group, the unaffected side was 12.9 % greater (more negative) than the unaffected side. In the experimental group, the

unaffected side values were 8 % greater using shoes and 4.6 % using DAFOs, and 37.4 % using shoes and 40.3 % using DAFOs, for the fast and slow walkers, respectively.

Table 3.48 Summary of statistical tests (paired *t*-tests) on minimum thigh velocity determinations for the experimental group according to fast (*n* = 5) and slow (*n* = 4) walkers status (affected side).

Group/ test	Mean	95.0% CI	*p*
Fast/ Test I	-0.03	(-15.73, 15.67)	0.996
Fast/ Test II	-5.63	(-32.83, 21.58)	0.597
Fast/ Test III	3.17	(-10.84, 17.18)	0.564
Slow/ Test I	2.33	(-29.13, 33.78)	0.829
Slow/ Test II	7.57	(-22.30, 37.45)	0.479
Slow/ Test III	-8.78	(-26.63, 9.06)	0.215

Maximum thigh velocity

For the control group (*n* = 3), on the affected side, the average maximum thigh velocity recorded was 3.7 % higher compared to that of the fast walkers (*n* = 5) using shoes, and 21.6 % higher using DAFOs. In contrast, the experimental group slow (*n* = 4) walkers' maximum values were clearly lower than for the control group, with 155 % and 133.7 % differences apparent with shoes and DAFOs, respectively.

On the side unaffected by stroke, the differences between the control subjects and the experimental group fast walkers maximum values were similar to the affected side, whereas comparisons with the slow walkers revealed clear differences of 57.5 % with shoes and 60.9 % with DAFOs.

Within-experimental-group data analyses were performed as previously described (values < 0.0 define results where maximum thigh velocity was better when shoes were used, and values > 0.0 indicate better thigh velocity when a DAFO was used). The data

were found to be normally distributed (Ryan-Joiner test, not shown). The paired *t*-tests failed to identify statistically significant differences between the values recorded for the DAFO and shoes condition on the subjects' side unaffected by stroke (Table 3.49).

Table 3.49 Summary of statistical tests (paired *t*-tests) on maximum thigh velocity determinations for the experimental group (exp, $n = 9$) using shoes and a DAFO (affected side).

Group/ test	Mean	95.0% CI	*p*
Exp/ Test I	-1.38	(-14.65, 11.88)	0.816
Exp/ Test II	2.02	(-16.26, 20.31)	0.805
Exp/ Test III	-6.98	(-21.19, 7.23)	0.290

Fast ($n = 5$) and slow ($n = 5$) walker analyses revealed no significant difference ($p > 0.05$) in maximum thigh velocity values using DAFOs compared to using shoes over the three tests during the 12 weeks testing trial (Table 3.50). Consistently negative mean maximum thigh velocity values were apparent for the slow walkers over the three tests, suggesting that the mean difference indicated positive effect with shoes compared to DAFO use. Although, this mean value demonstrated better results with shoes use, CI values indicated a large variability between subjects.

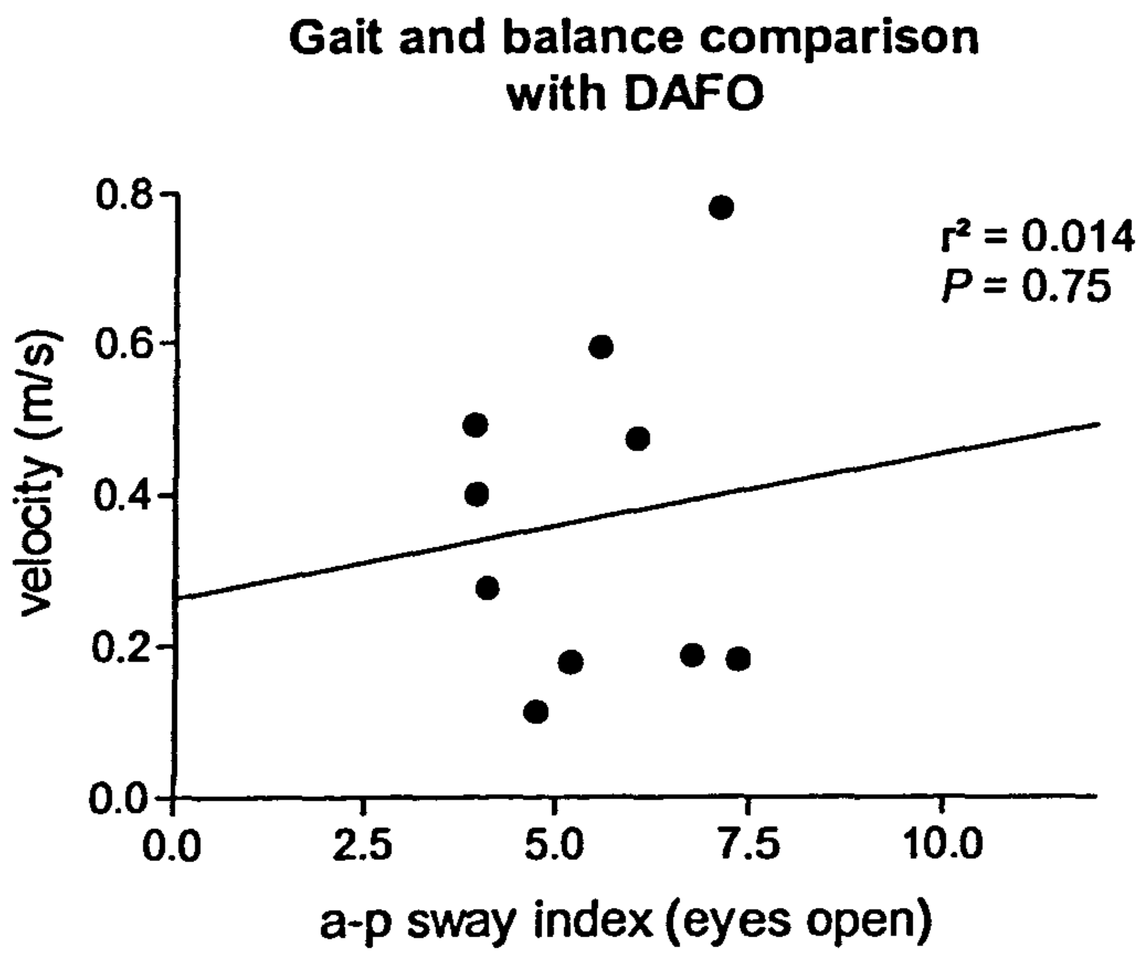
Table 3.50 Summary of statistical tests (paired *t*-tests) on maximum thigh velocity determinations for the experimental group according to fast ($n = 5$) and slow ($n = 4$) walkers status (affected side).

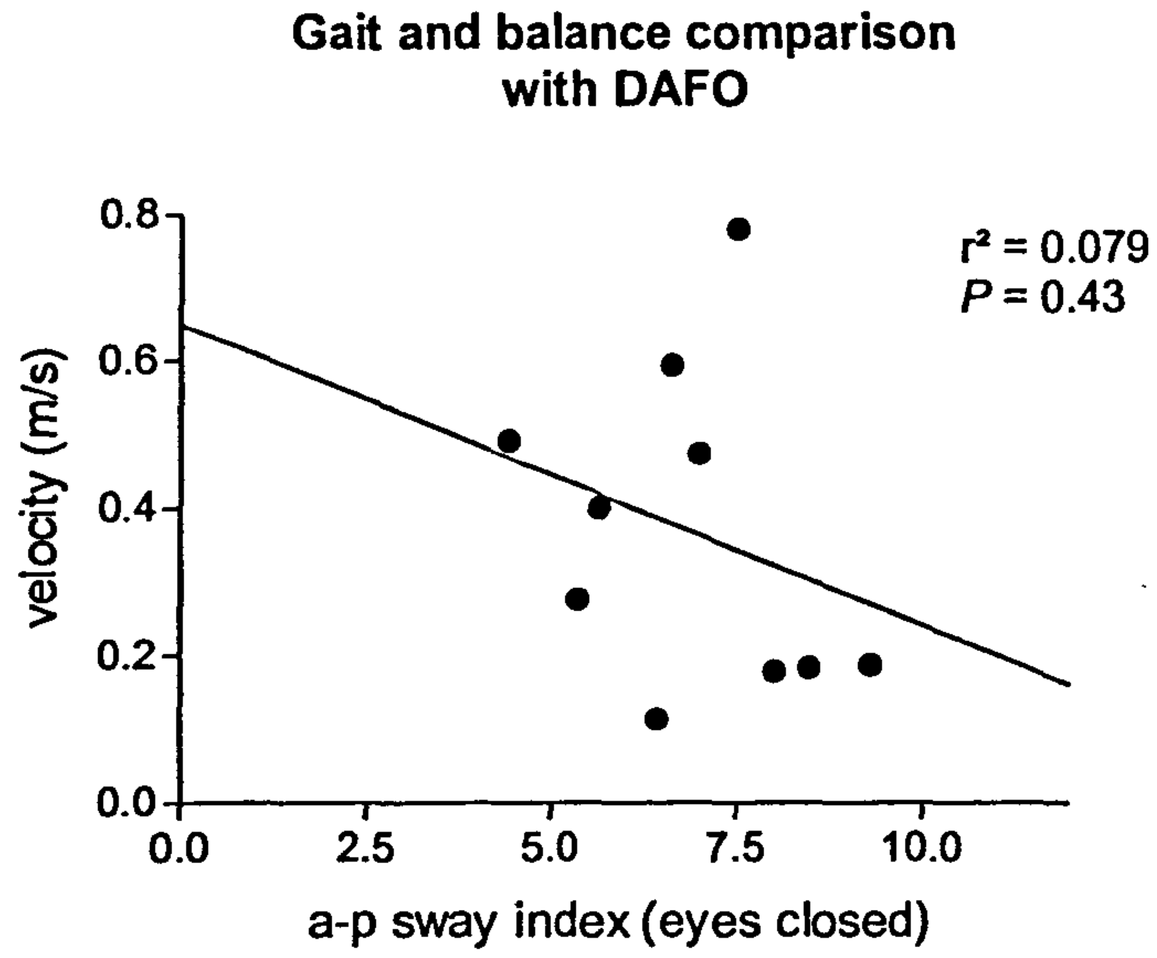
Group/ test	Mean	95.0% CI	*p*
Fast/ Test I	-2.07	(-15.84, 11.69)	0.697
Fast/ Test II	7.5	(-27.7, 42.7)	0.586
Fast/ Test III	-10.76	(-29.82, 8.30)	0.192
Slow/ Test I	-0.5	(-40.4, 39.4)	0.969
Slow/ Test II	-4.83	(-33.52, 23.86)	0.629
Slow/ Test III	-2.3	(-39.3, 34.8)	0.859

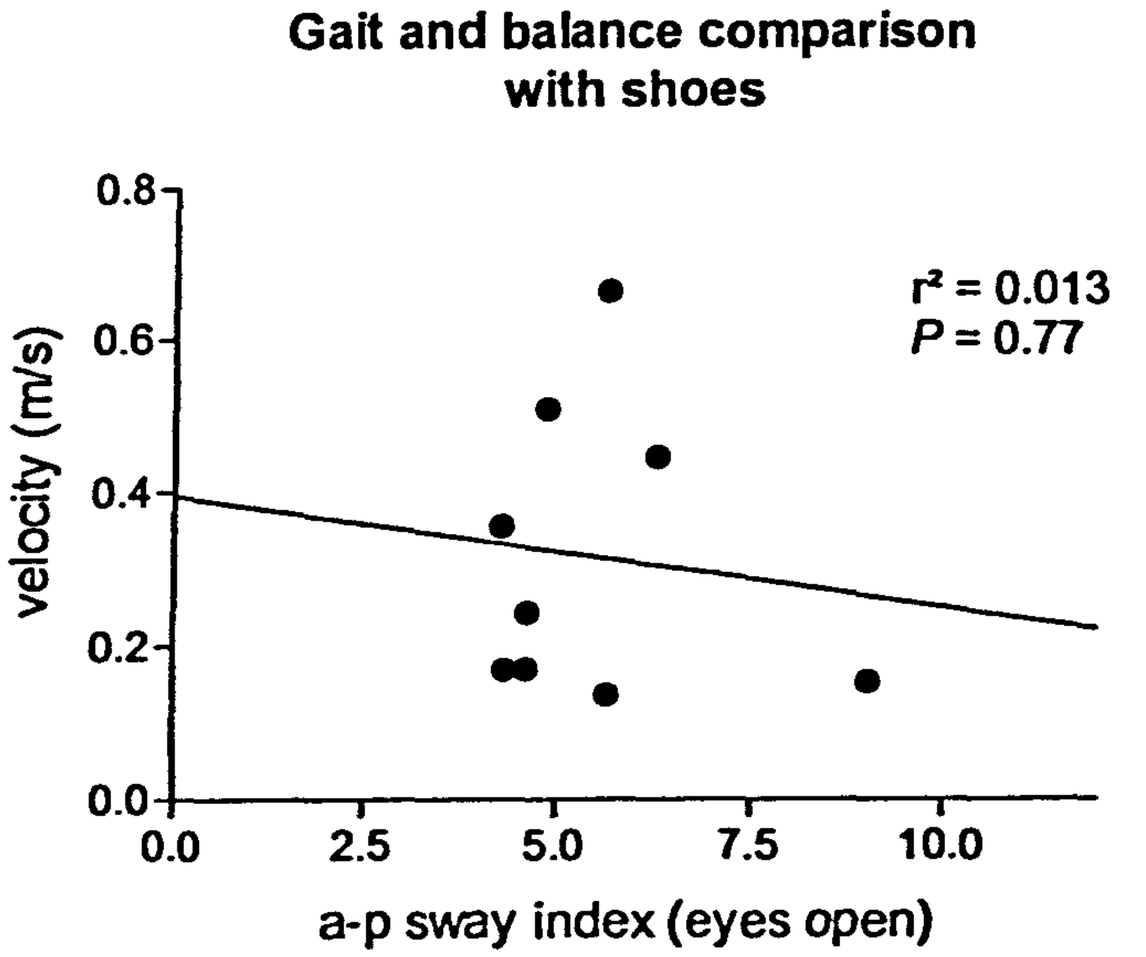
For both groups, the values determined on the side unaffected by stroke were closer to the healthy subjects' data than were the values obtained on the affected side. In the control group, the unaffected side mean values were 49.7 % higher than the unaffected. In the experimental group, the unaffected side values were 67 % higher using shoes and 75 % using DAFOs (fast walkers) and 171.7 % using shoes and 143 % wearing DAFOs (slow walkers).

3.3.1.5 Correlation between balance and gait

The relationship between the balance variables (CoP sway index, and antero-posterior and lateral Shear Forces) and gait velocity was also assessed. Figure 3.29 illustrates representative data, which were analysed using bivariate correlation (2-tailed Pearson's analysis). These comparisons indicated that the gait velocity in the experimental group using shoes or DAFOs did not correlate significantly with the balance variables. Similar findings have been published previously on studies of AFOs (Mojica *et al.*, 1988; Winstein *et al.*, 1989; Wade *et al.*, 1997). Wade and colleagues (1997) compared spatio-temporal walking parameters with the postural sway, and found no statistically significant connection between standing balance, walking parameters or functional abilities in 13 severe traumatic brain injury patients tested between 2 and 6 weeks apart. Wade suggested that improvements in standing balance are controlled by different mechanisms than those controlling improvements in walking performance (Wade *et al.*, 1997). In the present studies, the small sample size may have strongly influenced the findings. However, when subject's data were assessed individually, the slowest walkers provided the poorest balance values for all variables.







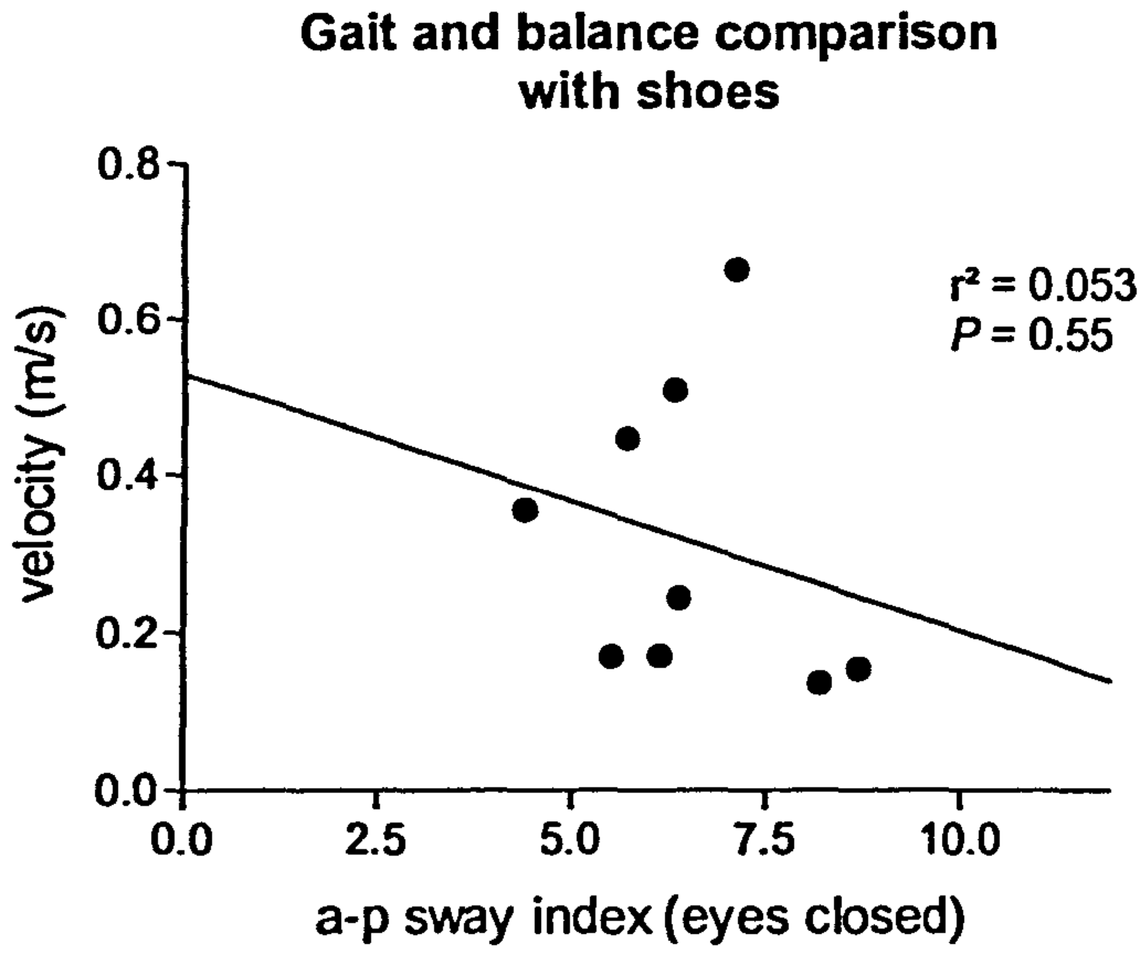


Figure 3.29 Comparision of gait velocity (m/s) and balance measurements (CoP sway index in a-p direction with eyes open and closed) using DAFO and shoes in the experimental group (n = 10). r^2 and p values, and lines of linear regression are shown.

3.3.2 Discussion

The second studies within the main phase of this research aimed to examine the effects of DAFOs on stroke subjects' gait and their potential to improve the daily physical activities of these subjects. Gait characteristics of 13 stroke patients were recorded simultaneously for the affected and unaffected leg using a three-dimensional, four-camera, movement analysis system. The gait velocity, stride length, step length, cadence, and single stance phase were studied along with the minimum/maximum values of the angular displacement and velocity of the foot, shank, and thigh segments in the saggittal plane during two strides. Again, multiple gait parameters were investigated because it is unknown, in this case, which variable, or combination of variables, most accurately describes alterations in stroke subjects' gait. The decision to study these particular parameters was also based on the findings of the accuracy and reliability pilot studies, in which it was determined that segmental measures in the saggital plane were the most reliable. Gait comparisons were made between the control (shoes users) and the experimental (DAFO users) groups. Further comparisons were made within the experimental group subjects, under two different experimental conditions: using either the DAFO or shoes-only. As for the balance studies presented earlier, the rationale for this approach was the potential for identifying any direct effects of the DAFO from unrelated influences, such as learning or/and recovery effects.

It was hypothesised that DAFOs improve motor behaviour after stroke involving the acquisition of gait performance compared to when using shoes alone (Hypothesis II). Overall, these studies did not identify consistent differences between the gait parameter measures when subjects used a DAFO or shoes alone. Thus, statistical comparisons performed on a between- and within-group basis usually failed to achieve significance. The caveats associated with the statistical power of this research were discussed earlier. Here, further loss of subjects meant that one of the test groups (control) consisted of only three subjects. Consequently, for these studies, the basis of the

randomised controlled philosophy had essentially been lost. It may be argued, therefore, that Hypothesis II should be rejected i.e. the distributions of the data obtained from the DAFO and shoe users are not measurably different, and it may be concluded that there is no evidence that DAFOs affect these subjects' gait performance. However, as was suggested in relation to the balance investigations, the existence of some differences between data obtained under the different experimental conditions may make such a blanket conclusion unjustified. For the purpose of the present studies, a possibility was to dispense with any statistical analyses and simply to treat the data for the two groups (with/without the DAFO) descriptively. However, it was felt that an approach involving no statistical appraisal of the data could be open to criticism, and as such analyses could not detract from the value of the information, it was decided to proceed as planned, but with full appreciation of the limitations of the outcomes. This approach identified several variables of stroke patients' gait that were appreciably different between using DAFO and shoes. In some instances, the magnitude of these differences was sufficiently large to attain statistical significance. On these grounds, the author maintains that the sometimes obvious differences between gait data obtained for DAFO use and shoes use, may be of scientific or/and clinical importance, irrespective of the statistical outcomes, and that such findings warrant further consideration.

The findings of these studies may be summarised as follows. Within-experimental group comparisons demonstrated that, when a DAFO was used, subjects had increased gait velocity, improved stride length and single-stance phase, during walking in relation to their side affected by stroke (section 3.3.1.3). In addition, it was found that several of the saggital plane kinematic parameters were potentially sensitive to DAFO intervention. Thus, similar analyses showed that the minimum foot velocities (end of stance to early swing phase) of subjects classed as fast walkers were predominantly closer to normal levels when a DAFO was used compared to shoes (section 3.3.1.4). Minimum foot and shank displacements values (early swing phase) obtained following DAFO use, for the

entire stroke group, were also predominantly consistent with nearer normal levels compared to shoes. Higher maximum foot velocity values (middle of swing phase) were identified using DAFOs compared to shoes. All of these within-group comparisons achieved statistical significance in Test I, except minimum foot velocity, minimum foot displacement and minimum shank displacement. Notably, gait velocity was also increased ($p < 0.05$) in Test III when subjects used the orthosis compared to shoes alone. Contradictory findings, which suggested that shoes provided nearer normal values, were evident for minimum foot velocity (end of stance phase) for slow walkers during Test II ($p < 0.05$) compared to DAFOs. In addition, the maximum thigh velocity (early swing phase) of the slow walkers most often indicated nearer normal levels associated with shoe use.

In order to develop a rational overview of the possible implications of these spatio-temporal and kinematic findings in relation to stroke patients' gait, it is logical to consider them individually and collectively and, in some cases, with respect to the order in which they were obtained (and therefore reflect) during the gait cycle.

Spatio-temporal parameters of gait

The finding of an increased gait velocity within the experimental group when wearing the device suggests positive effects due to DAFO use. Patients' self-selective gait velocity is a well-established indicator of overall gait performance and increases with recovery of motor function (Potter *et al.*, 1995; De Quervain *et al.*, 1996; Kwakkel and Wagenaar, 2002; Lamontagne *et al.*, 2002). The relationship between poor levels of this parameter (slow gait velocity, < 0.25 m/s) and the use of various walking aids, fall frequency, and other measures of mobility, has also been documented (Potter *et al.*, 1995; Richards *et al.*, 1995; De Quervain *et al.*, 1996).

In the current study, the large variation in gait velocity suggested separation of the experimental group into two sub-groups, 'slow' and 'fast' walkers. Such division of

subjects into sub-groups is commonly used in studies of this type (De Quervain *et al.*, 1996). However, it is emphasised that here the use of the term 'fast' is only relative to the gait velocity of the 'slow' walkers; the 'fast' walkers mean gait velocity was 0.53 m/s, which is consistent with severely disabled individuals (De Quervain *et al.*, 1996). Extremely slow gait velocity values for the slow walker group (mean 0.19 m/s) are in accord with the findings of low ADL scale scores reflecting even more severe disability (Potter *et al.*, 1995; De Quervain *et al.*, 1996; Wooley, 2001).

Here, the potentially beneficial effect of the orthosis during the early stages of the intervention, as indicated by consistently increased gait velocity in Test I, was an interesting finding. This influence was also present (albeit less noticeably) in Test III, which corresponds to the later stages of the research period. It is notable that Test I cannot be described as a genuine 'baseline' test. In order for subjects to become accustomed to their DAFO, the patient-specific (customised) device was supplied to each experimental subject, who became accustomed to wearing it for approximately 6-8 hours per day took, some weeks before the measurements commenced. Whilst the effect of the DAFO on gait velocity was still evident ($p < 0.05$) after 12 weeks, the velocity differences existing between the DAFO and shoes conditions were less noticeable. The reason for this was unclear, although division of the data according to walking speed provided a possible explanation. Thus, the fact that the potentially useful effects of the DAFO on gait velocity in Test I were seen primarily for the slow walkers, who were more severely disabled, suggests that the effect was already maximal, due to energy and functional limitations, and that their gait velocity could not increase over further weeks. Alternatively, it is possible that this situation reflects, at least in part, a 'learning' effect, and that this influence was more pronounced in Test I than in Test III. It is possible that such learning effects could mask DAFO related-actions. In addition, spontaneous neurological recovery of stroke patients enables some functional recovery, which could also obscure treatment effects (Kwakkel *et al.*, 1999).

Improved gait velocity is believed to be associated with coordination of walking, and several clinical trials have provided evidence indicating that gait velocity may be used as an independent variable in the evaluation and treatment of gait disorders (Wade, 1992; Hesse *et al.*, 1995; Kwakkel and Wagenaar, 2002). Based on these assumptions, and the findings of this study, it may be argued that use of a DAFO can improve these subjects' gait velocity over the research period (12 weeks). DAFOs may therefore be of benefit in the gait rehabilitation of non-acute stroke patients such as these in their home environment.

In earlier studies, which have examined other types of splints on stroke patients' gait, determination of gait velocity has been a focus. Overall, these reported works indicate that several types of AFOs (including DAFOs) increase the gait velocity of stroke subjects (Leung and Moseley, 2003). Prior single-case design studies of DAFO effects on stroke subjects' gait have concentrated mainly on their potential to alter the temporal parameters of walking. The present work is consistent with those earlier studies in that similar, positive effects of DAFO were indicated in relation to gait velocity (Uutela and Bowker, 1998). The present research is also notably consistent with earlier reports in which DAFOs were compared with shoes (Mueller *et al.*, 1991), and where positive DAFO effects were obtained by comparisons with the device and barefoot walking (Diamond and Ottenbacher, 1990; Mueller *et al.*, 1991; Wolley *et al.*, 1996).

It is reasonable to expect that the positive effects of any orthosis would be easier to demonstrate in comparison with a barefoot situation as opposed to shoes. Hesse and colleagues (1996) compared the gait velocity data of 19 stroke patients' collected walking barefoot, using shoes-alone and with a conventional AFO. These authors reported that although gait velocity was improved significantly by the AFO, better velocities were also apparent for the shoes-alone condition compared to barefoot walking. During daily living, disabled and older stroke subjects rarely walk barefoot. In general, stroke patients feel less confident when walking without shoes. In the present

studies, all of the subjects preferred to walk with their own shoes than barefoot. It is perhaps reasonable to assume that the experimental conditions adopted for the present studies represent a more natural and practical situation, particularly for older stroke subjects, who usually walk using conventional shoes only. It is therefore a possibility that the testing procedures used here provide a more reliable indicator of the potential for DAFO mediated effects. However, there is scope for further debate on whether a full appreciation of the extent of these effects requires additional knowledge of the action of the device in comparison to the barefoot situation. Thus, models of AFOs other than DAFOs were tested recently and compared to barefoot walking, and positive effects were found associated with splint use (Gök *et al.*, 2003).

Earlier gait studies have demonstrated a linear relationship between increased gait velocity and an individual's longer stride length (Winstein *et al.*, 1989). The finding of potentially positive effects of the DAFO, as evidenced by increases in subjects stride length during Test I, which was evident for all experimental subjects, is likely to be a function of the improved walking velocity. The observation that single stance phase was also clearly longer with DAFO than with shoes use in Test I may be explained by the DAFO imparting supportive functions via mechanical support of the ankle, which increases the single stance phase duration, thereby improving weight bearing over the affected leg. This suggests that the extremely lightweight and low profile orthosis can still provide reasonable levels of mechanical support for the foot and ankle such that, for some stroke subjects, use of the device may promote increases in single stance duration. The present finding is also consistent with the notion that the DAFO might enable improved weight bearing, an action which is believed to help stroke subjects' walking ability, and thereby decrease the severity of motor dysfunction (Gaviria *et al.*, 1996). The lack of appreciable effects of the DAFO in Test II and Test III may be explained by a learning effect associated with use of the splint, or physical limitations imposed by these subjects' disabilities. Thus, single stance phase duration is

particularly sensitive to the severity of stroke patients' disability and difficulty in increasing this parameter is well documented (von Schroeder *et al.*, 1995). The results of the present studies are consistent with those of Diamond and Ottenbacher (1990) and Dieli (1997) who, following single-case experiments, also reported positive effects of DAFOs on stride length and single stance phase. The present investigations, which were conducted on a larger sample population of stroke subjects using DAFOs, therefore support earlier, less comprehensive studies (Uutela and Bowker 2003). Furthermore, the results presented here extend knowledge, by providing novel evidence for potentially beneficial alterations in single stance phase duration of stroke subjects attributable to a DAFO, in relation to severely disabled and older aged subjects during the initial (< one year) recovery and non-acute post-stroke period.

Recently, evidence was obtained to suggest that increased single stance duration is also evident using another type of orthosis. Hesse and colleagues (1999) tested 21 stroke subjects with a conventional AFO (Valens calliper) and found that whilst no increases in gait velocity could be associated with the device, the single stance duration increased with the AFO compared to walking with shoes alone. Determination of this parameter provides further details of the gait pattern, especially with regard to stability and control of muscles, when bodyweight is carried by the 'single-stance leg', at the point at which the other leg enters swing phase. Single-limb stance is believed to be a good indicator of leg support stability and ankle plantar flexor power (De Quervain *et al.*, 1996; Judge *et al.*, 1996). In addition, Gaviria *et al.* (1996) suggested that single stance support on the affected side is one indicator that may signify the severity of motor involvement. In the current study, both control and experimental group stroke walkers had an approximately 10 to 15 % shorter single stance phases than the healthy subjects, and always displayed a clearly asymmetrical gait pattern, with a longer single stance phase on the unaffected side. The spatio-temporal gait findings of these studies (section 3.3.1) also provided data that were consistent with the well-established gait

deficits that are characteristic of stoke sufferers. Gait performance (as indicated by all of the variables monitored) was poorer for the stroke patients than for the group of similarly aged healthy subjects. Earlier studies have described how stroke patients exhibit gait deviations that differ significantly from those of healthy normal individuals using a variety of quantitative methods, including movement analysis (Dannenbaum, 1982; Wooley, 2001).

Gait kinematics

The control and experimental groups exhibited similar segmental characteristics to the healthy subjects throughout the full gait cycle. Differences, however, were found in the large variability of motion of the curves with clearly reduced peak value displacements and velocities in late stance, pre- and mid- swing phases. These indicated impaired weight transfer and push-off during late stance, and limited clearance of the floor on the affected leg during swing phase. The slow walkers group displayed the clearest kinematic gait deviation from the accepted norm (section 3.3.1.3). Earlier studies of gait deficiencies in stroke patients support these findings (Olney *et al.*, 1994; Richards *et al.*, 1995; Hesse *et al.*, 1996; Lamontagne *et al.*, 2002).

Late stance phase

The minimum value of the foot angular velocity is normally achieving during the late stance to early swing phases, when ankle joint maximum plantarflexion is achieved (Figure 1.1). Foot plantarfexion motion was shown to be clearly reduced in stroke subjects compared to healthy subjects, and is believed to be related to the degree of calf muscle spasticity (Lamontagne *et al.*, 2001) and weakness (Lamontagne *et al.*, 2002) that can lead to overall ankle joint instability (De Quervain *et al.*, 1996). Here, it was found that the minimum foot velocity of four of the five (fast walker) subjects tested yielded values during late stance phase that were consistent with a positive effect of the DAFO compared to shoes alone, throughout the three testing sessions. This

observation suggests a more effective push-off phase, possibly due to a DAFO-mediated improvement in medio-lateral stability, which supports 'striking' (toe contact with the ground) via better support of the weak plantar flexor muscles, which is typical for stroke subjects. It is possible that this effect may be a function of the construction of the splints (low and flexible) which, as was proposed, allow movement during extension and, consequently, better motion when the ankle and knee joints transfer forward forces via hip extension in late stance phase. In addition, this action may be associated with reflex activation (proprioceptive) via splint support during the stance phase, which activates leg extensor muscles under the influence of gravity (Dietz and Duysens, 2000).

The observation that this potential influence on stroke subjects' gait was mainly specific to the fast walker group is an interesting finding. The mean walking velocity of those subjects was 0.53 m/s, which approximates that of stroke walkers' gait speed when there is severe gait disability, but with reasonable levels of daily activities (Potter *et al.*, 1995; Kwakkel and Wagenaar, 2002). Provision of AFOs to such patients is rarely considered necessary in the U.K, as it is assumed that benefits are unlikely to be forthcoming, and that the device may induce further asymmetrical gait (Lennon *et al.*, 2001). The potentially useful influence of the DAFO suggested by the present work may imply that these subjects could benefit from use of the device. Such influences are also likely to be beneficial in relation to stroke subjects' overall walking capability, as improved joint mobility may enhance the efficiency of late stance phase function, which provides contra-lateral propulsive forces and generates sufficient moment to initiate hip flexion. However, clearly the large 95% CI values and lack of statistical significance of differences between DAFO and shoe users when these results were considered on an entire group basis means that verification of these ideas will require further study.

Interestingly, the present studies identified a contradictory finding with respect to the minimum foot velocity values of the slow walker group, where an obviously positive

effect associated with shoe use compared to the DAFO was apparent. This disparent result, which was only apparent in Test II, suggests that the DAFO might not provide sufficient ankle-foot support for slow walkers who have severely limited muscles activity and/or muscle spasticity (not tested in this study) at the ankle joint. Alternatively, the finding may be consistent with earlier studies of the effects of other AFOs on stroke subjects' ambulation, which described a lack of effect on joint function, particularly during late stance phase. In those studies, it was suggested that this discrepancy could be due to excessive, passive support provided by the AFO, combined with the particularly weak ankle joint motion of some subjects (Lehmann *et al.*, 1987). Thus, some older type of orthoses, which were constructed using less pliable material and had higher trim-lines, may result in significantly stronger fixation of the ankle than the device used here. The present finding indicates that the DAFO may also provide too much passive support for some stroke subjects. The reason why such effects were only apparent in test II (after 4 weeks) is unknown; further studies are required to resolve these issues.

Early swing phase

The minimum displacement values of the foot and shank angulations, including maximum thigh velocity, are normally achieving during the early swing phase (Figure 1.1), and associated with large ankle plantar flexion and knee extension and hip extension indicating a change in the direction of movement (Lehmann *et al.*, 1987; De Quervain *et al.*, 1996; Olney and Richards, 1996). In the present studies, the measures of minimum foot and shank angular displacement differences were mostly consistent with positive effects attributable to the device compared to shoes alone. Minimum shank displacement differences for six of the nine experimental subjects suggested positive effects associated with DAFO use. Foot angular displacement differences for four of the five subjects classified as fast walkers indicated potentially beneficial effects of the DAFO. However, it is known that stroke patients often experience severe difficulties in

ankle motion during early swing phase (De Quervain *et al.*, 1996). The foot drag on the affected side during early swing phase is a typical feature of stroke patients' gait, which is probably due to muscle weakness and partly hyperactivity of the calf muscles (Lamontagne *et al.*, 2002). Ankle and knee dorsiflexion are limited, and progression to the middle of the swing phase occurs particularly slowly. A positive correlation between ankle plantar flexor and knee extensor muscle strength and gait velocity has been reported in studies of the early swing phase of healthy elderly subjects (Prince *et al.*, 1997; Haghani and Marks, 2000). In addition, the relationship between poor ankle plantar flexor strength and shorter step length, resulting in a poorer gait pattern is well established (Judge *et al.*, 1996). The observation that some subjects indicated potential benefit due to DAFO use in the early swing phase, suggests that the device might also improve ankle plantar flexor muscle function by medio-lateral stability of the ankle joint and thereby facilitating better gait control. Possibly, the low construction of the DAFO, which nonetheless retains flexibility during motion, may support the weaker muscles' ability to produce power during the early swing phase. Thus, beneficial support of the foot provided by the DAFO may lead to concurrent changes in the more proximal shank motions. The reason why some subjects did not provide values consistent with positive effects of the DAFO is unclear. The level of subjects' usual gait velocity (relatively fast or slow) or daily functional ability does not explain this inconsistency.

The results obtained for minimum shank and maximum thigh velocities in the early swing phase, which indicated no clear improvement of function on the affected side of the experimental subjects, are inconsistent with those obtained for the segmental displacement work. Interestingly, the mean peak thigh velocity value of the slow walker group suggested that shoes might be more beneficial than DAFOs with respect to this variable. Nevertheless, when individual differences were considered, only one of the five subjects indicated nearer normal maximum thigh velocity during shoe use. This observation highlights the potential for obtaining artefactual results following statistical

analyses on groups containing small numbers of subjects. Thus, here, one subject provided a maximal thigh velocity value that was especially negative in relation to DAFO use, whereas the other four subjects provided values consistent with positive effects of the DAFO, but within a narrow range. It is also notable that the preliminary studies demonstrated (section 3.1.1.3) that hip joint motion measures provided the poorest reliability results, which may also be a contributory factor in the inconsistencies in thigh measurements results described here. It is notable that none of the results for the segmental displacement and velocity measures obtained during early swing phase indicated any clear benefits associated with DAFO or shoe use on the subjects' side unaffected by stroke.

No earlier studies have been reported describing the effects of DAFOs on stroke subjects gait during early swing phase. Following experiments using other types of AFO, Burdett *et al.* (1988) observed that conventional AFO, polypropylene AFO and air-cast AFO had no clear effects on stroke patients' ankle and knee joint motion during swing phase, although all these orthoses affected ankle plantarfexion, which was reduced during swing phase. It is notable that the potential for effects of these orthoses on early swing phase were not considered.

Mid swing phase

The peak values for foot and shank velocity were achieving during the middle of swing phase, when joints movements are changing direction, with large ankle and knee flexion motion. These events are critical when taking a step forward successfully (Roberts *et al.*, 1997; Wooley, 2001; Lamontagne *et al.*, 2002). The potential for improved gait following DAFO use compared to wearing shoes, as implied by the maximum foot velocity parameter, was clearly ($p < 0.05$) apparent in the middle of swing phase. This is a novel finding of DAFO effects on stroke subjects' foot kinematics, and indicating that DAFOs may modify these subjects abnormal gait pattern towards normality by supporting the ineffective ankle dorsiflexors during the swing phase (Uutela and

Bowker, 2003). Such actions were apparent for all of the experimental subjects and were particularly clear on the side affected by stroke. However, this encouragingly positive effect attributable to DAFO use was only apparent in Test I, with no further differences pointing to long-term improvement over the 12 weeks study time.

Lehmann *et al.* (1986) reported similar actions on stroke subjects' mid swing phase following use of a different AFO design to that used here. These effects were attributed to splint-mediated mechanical support of the ankle joint afforded by dense polypropylene material. In addition, recently, Gök and colleagues (2003) obtained similar positive findings in the swing phase of gait cycle with conventional AFOs and a polypropylene AFO, when data were compared with barefoot walking. The present work involved a device fabricated from a much more flexible material (stretched homopolymere polypropylene), with a lower construction than many earlier AFO designs. The work reported here provides unique evidence to suggest that the DAFO can also provide reasonable support to the foot and ankle when clearing the floor during the swing phase of these stroke subjects on the affected side (Uutela and Bowker, 2003).

Earlier studies of stroke patients' gait problems have shown that the flexion of hip, knee and ankle motions are limited, which causes difficulties when lifting the foot to clear the floor during swing phase, and taking a further step safely (De Quervain *et al.*, 1996). In addition, without proper flexion of lower limb joints, the leg clears the floor by compensation using more predominantly the proximal muscles, which is a typical characteristic of the hemiplegic gait pattern (Evans *et al.*, 1997). As was identified by Nadeau and colleagues (1999b), stroke subjects' have the ability to use compensative pelvic elevators for the weak ankle plantar and dorsiflexor muscles, which are already at maximal activity levels during swing phase. This pelvic compensation minimises the ankle flexion motions during late stance phase and early and mid swing phase. The results of the present work suggests that, for these experimental subjects, ankle flexion

motion improves with DAFO use, which may aid the subjects when initiating and progressing the movements that cause the foot to clear the floor during swing phase.

The reason for the absence of differences in thigh variable values (minimum displacement and maximum velocities) with DAFOs or shoes measured during the middle and late stance phases is unclear. This suggests that DAFO intervention does not affect the hip joint movements during swing phase. However, it is reported elsewhere that hip motions are severely abnormal with stroke walkers (De Quervain *et al.*, 1996). It is therefore possible that such extreme deviation and variation in hip movement during stroke patients' gait masks treatment effects. Further studies are needed with larger subject numbers to assess this possibility. The present findings of some improvements of foot motions during mid-swing phase wearing a DAFO indicate that these devices may have potential for ameliorating walking deficits with these patients' gait rehabilitation. This proposition is subject to several limitations of the work, which are addressed later.

In both groups the spatio-temporal and kinematic parameters for the unaffected side indicated clear differences compared to the affected side (where asymmetry was evident) with nearer normal parameters on the unaffected leg. In addition, it was found that when data was collected simultaneously both legs, the slow walkers pointed to more severe asymmetry between affected and unaffected legs than the control group, or the fast walkers.

In this study, the gait of stroke subjects was evaluated in detail using advanced gait assessment methods. Generally, these studies did not identify consistent statistically significant differences between the gait parameters when subjects used a DAFO or shoes alone. With this limited number of subjects, no definitive evidence was obtained to support the idea that DAFO use imparts beneficial effects on stroke subjects' gait performance. However, this present research suggested that some gait parameters might be influenced by a DAFO. DAFOs may alter certain spatio-temporal aspects of

walking, including foot kinematic variables, which occur during late stance, pre-swing and mid-swing phases. Some anecdotal evidence was obtained pointing to beneficial effects associated with DAFO use by stroke subjects, in relation to ankle and knee joint motions, with less clear effects on the more proximal joints. The potential for these positive effects of the DAFO was most evident in Test I; long-term effects over three months could not be established. The clinical implications and limitations of the novel findings identified by this research are addressed later.

3.4 Main phase - Subjective feedback

3.4.1 Results

This section presents the results of questionnaire assessments designed to determine experimental subjects' subjective opinion concerning the ease of use and any benefits gained when using a DAFO (Appendix III). These assessments were carried out after modifications indicated by the preliminary work presented earlier (section 3.1). The questionnaire was completed after the balance and gait tests and functional assessments within each testing session.

Eight subjects required help when putting on the DAFO throughout the entire testing time (3 months) and, of these subjects, 3 also needed assistance when removing the splint. However, it was noted that due to the level of their disability, these 3 subjects were also dependent on assistance when dressing. For those subjects who needed help donning and/or doffing the DAFO, 4 indicated that their partner helped them to fit the DAFO, 2 were assisted by a carer, and 1 was aided by her husband and son. Six of these subjects also indicated that they required help when dressing. In test I, the subjects indicated that their daily DAFO use averaged 8 hours (range 4 - 12) per day. For tests II and III, the average usage increased to 9.3 h (range 5 - 14) and 9.7 h (range 3 - 14), respectively. The results of these assessments are summarised in Figure 3.30.

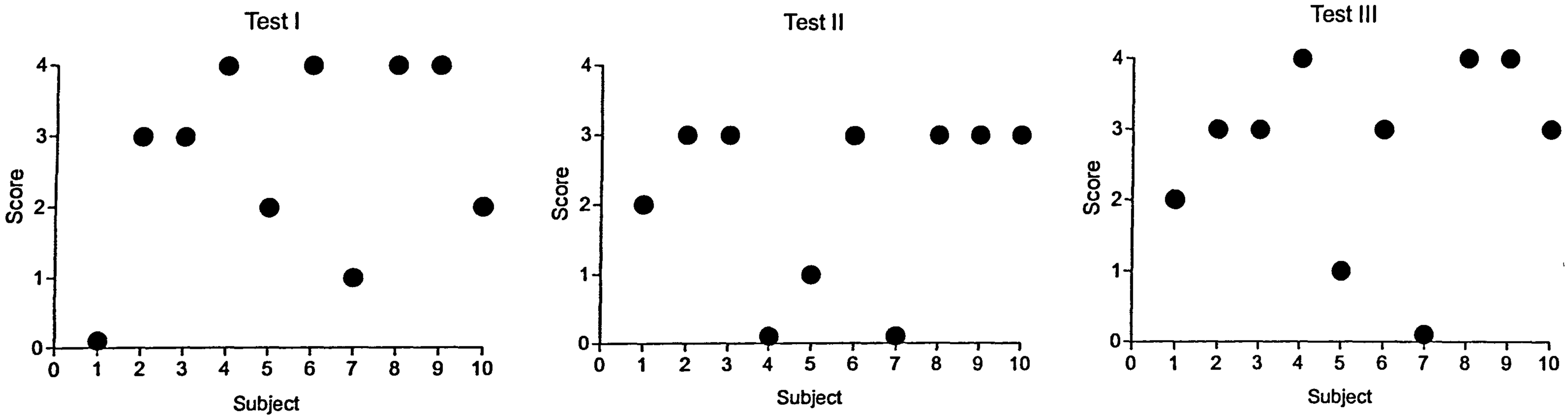


Figure 3.30 Subjects' opinions provided in a questionaire set and designed to determine ease of putting the DAFO provided on and removing it. Subjects' (n = 10 in the x-axis) scored their answers on a scale of 0 - 4 (very difficult - no problem in the y-axis) as detailed in Methods.

When the questions on how the subjects' found fitting the DAFO in terms of ease and overall comfort and benefits when walking were scored, it was found that in test I, 4 of the 10 subjects reported no problems (score 4) when donning or doffing, the DAFO, although 2 of these subjects had answered earlier that they did need help when fitting the orthosis. Six reported difficulties: 2 felt that the device was 'mostly comfortable', 2 entered 'sometimes difficulties' and 2 subjects provided scores of 1 or 0, indicating that the task was 'always difficult' / 'very difficult'. After one month of use, all subjects reported some level of difficulties when putting the DAFO on / off and 2 felt that it was 'always very difficult'. In test III, after three months use of the splint, higher scores were recorded. Thus, 3 subjects indicated 'no problems', 4 'mostly comfortable' and only 3 subjects scored 2 or lower. Three of the subjects felt that they had 'learned' to fit and remove the DAFO during the three month period; 1 subject felt that leaning backwards slightly helped when taking the DAFO off, although adopting this posture had no obvious effect when donning, which remained a difficult task.

Overall, the subjective opinions provided by the patients summarised above revealed that they did experience difficulties when putting the splint on and removing it. In contrast, the patient feedback for actual use of the DAFO gave very positive and encouraging results (Figure 3.31). Eight subjects indicated that use of the DAFO did not involve any problems, and only 2 felt that the splint was sometimes difficult to use (test I). In test II, 3 of the subjects thought that the DAFO was 'mostly comfortable' and just 1 indicated that DAFO use was 'sometimes difficult'. In test III, 7 of the subjects experienced no problems and only 3 provided a score of 1 or 2. Four of those subjects who gave a score of 3 or less explained the reasons for their decisions. These were:

- red mark on the little toe due to pressure of shoes;
- using the DAFO for many hours gave a 'funny' feeling in the foot-ankle area - splint supported foot too strongly;

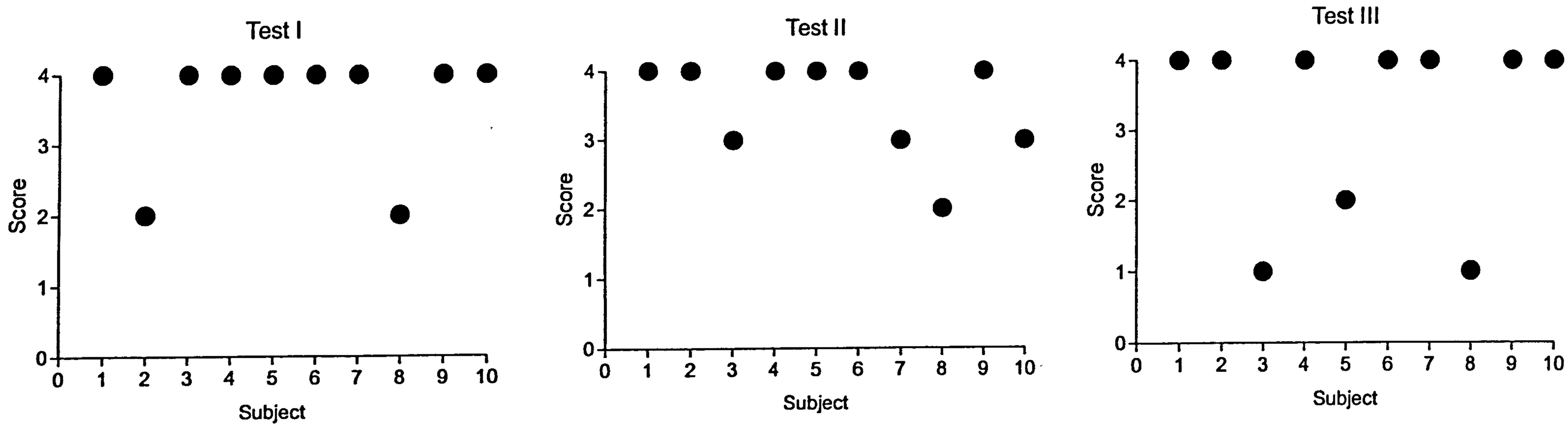


Figure 3.31 Subjects' opinions provided in a questionaire set and designed to determine the ease of actual use of the DAFO provided. Subjects' (n = 10 in the x-axis) scored their answers on a scale of 0 - 4 (very difficult - no problem in the y-axis) as detailed in Methods.

- difficulties with the velcro strap because they only had use of one hand (2 subjects).

Similar responses were obtained for the question aimed to determine the subjects' perceived ease of walking with the DAFO. Thus, 2 subjects felt some discomfort in test I, and 3 subjects in tests II and III. The range of scores recorded was 1 - 3 (Figure 3.32). Of those subjects who reported some difficulties, subject number 3 indicated that the discomfort was due to 'pressure area around little toe', which caused a red mark after a long walk; the splint also felt 'very hot after some hours use'. Subject number 5 felt that her foot was heavier because she needed to use over-sized shoes with the splint. Subject number 8 also felt that the foot was very hot when wearing the DAFO and experienced some pressure in the front ankle region.

The 8 patients who provided positive overall opinions of the DAFOs all indicated that they firmly believed that the device helped them when walking. These subjects commented that:

- it was 'easier to lift the foot up'
- that the 'foot feels more firm, keeps foot flat on the floor'
- 'feels good and gives confidence'
- 'assists walking, keeps foot straight, toe relaxed'
- 'foot feels more sensitive'
- 'step easier to take, DAFO follows my foot well'
- 'walking is quicker and help me to control my body'
- 'better to walk, easier to keep heel down when taking a step and then push with the toes'
- 'feels good to use'.

Figure 3.32 Subjects' opinions provided in a questionaire set and designed to determine any benefits perceived when walking using the DAFO provided. Subjects' (n = 10 in the x-axis) scored their answers on a scale of 0 - 4 (no mprovement - considerable improvement in the y-axis) as detailed in Methods.

3.4.2 Discussion

Over the 3-month study period, the overall findings for subjective feedback were extremely positive. It is notable that the patients' own comments improved as the study progressed. Thus, the results indicate that during the first month the principal problem with using the DAFO concerned donning ('difficulties to put on' score). After a short period this became less problematic. As several of the patients' kin assisted (actively) throughout the trial, a logical explanation for the improvement is that the subjects became more accustomed to and proficient in using the device.

A notable finding was that 8 of 10 patients expressed a positive opinion of the benefits they perceived when using the splint and wished to continue use in every day life after conclusion of the experimental trial. The 3 subjects who reported difficulties using the splint indicated that the main reasons were technical: Velcro strap changes or their own shoes caused pressure. Only one subjects experienced excessive pressure over the foot and ankle. Such feedback emphasizes the necessity for regular follow-up (questionnaires) after orthosis clinics, in order to provide the therapist and orthotist with vital information required when making appropriate changes to the splint prescribed. Indeed, this objective was a primary purpose of these investigations.

Although occasionally comments were ambiguous it was clear that, overall, the subjects' were predominantly in support of benefits associated with use of the DAFO. For example, one consistently returned comment was that the splint 'feels' good, 'foot more sensitive' and 'helps the foot on the floor while take steps'. The most remarkable information gained from these studies was that 80 % of the DAFO users felt that the splint improved their walking ability. These objective investigations therefore provide striking evidence of the potential benefits of DAFOs. As already described, whilst there are a few earlier studies that have reported positive stroke patient feedback for conventional AFOs, the scientific literature contains no detailed reports where this approach was used to identify possible benefits associated with DAFO use. Diamond

and Ottenbacher (1990) used a single-case design to study the effects of a DAFO on the stride characteristics of an adult with hemiparesis, and commented that the subject felt the orthosis increased his ability to ambulate distances. Dieli *et al.* (1997), who focused on the effects of DAFOs on the gait of three hemiplegic adults using a single-session experimental design, also described the patients' subjective opinions of difficulties when donning and doffing the DAFO, and how the subjects believed that the device increased correction of their equinovarus position, and decreased fatigue when walking. The authors did not provide details of the method used for data collection during this part of their studies. Clearly, the difficulties patients encountered when putting the DAFO on and off found in the present investigations are consistent with those of Dieli *et al.* (1997). However, given the superficial nature of the earlier investigations, it is impossible to comment further on their relevance to the present work.

The overall paucity of information for subjective feedback and AFO use was commented upon recently in a review of the impact of these devices on adult hemiplegic subjects' ambulation (Leung and Moseley, 2003). Although the results of the subjective feedback studies reported here did not use a validated questionnaire, they are unique and provide novel evidence for the potential for beneficial effects of DAFO on stroke patients' ambulatory difficulties. It is notable that the convincing results of the subjective feedback studies appear to conflict with the findings of the quantitative balance and gait measurements presented earlier, which failed to provide compelling scientific support for a beneficial action of the device. The reason for this disparity is unclear. As all of the studies used the same patient cohort, the fact that a small sample population may have limited the statistical power of the quantitative studies cannot account for the discrepant outcome of the subjective investigations. It can be argued, therefore, that the subjective results may provide a more reliable indicator of the potential benefits of DAFOs than do the quantitative data. However, it is noted that whilst the quantitative studies were,

overall, unable to provide firm evidence for an influence (beneficial or otherwise) of the orthoses, many of the measures did point to the use of DAFOs conferring improvement in subject's performance. Although these indications rarely achieved statistical significance, it is noteworthy that most of the encouraging quantitative results were gained following analyses, which include a component that involves consideration of the data on an individual subject basis (e.g. in section 3.3.1.3). The qualitative studies undertaken here inherently consider subjects on this basis. Thus, certain aspects of the quantitative and qualitative studies were similar, in terms of the analytical approach used and, by simple extension of this relationship, both provided evidence supporting potentially beneficial effects of the DAFO. Whilst it is acknowledged that this idea is, at best, speculative, the unmistakable significance of the positive subjective feedback cannot be ignored and, consequently, it is proposed that further investigations of the device are warranted.

4 LIMITATIONS

1. It was extremely disappointing that many of the subjects initially considered for recruitment to this research project did not fulfil the experimental criteria. The reasons for insisting on these criteria have already been explained. The loss of subjects after the trials commenced, for other (sometimes personal) reasons was unavoidable. Time constraints imposed on the research were also a relevant factor. Of the 195 patients who were recruited and assessed, only 22 subjects were included in the main trial. To reiterate, this led to a limited number of subjects in each experimental group following randomisation, and consequently a reduction in statistical power. As the general stroke population is highly heterogeneous, in terms of pathology, disability levels and stage of recovery, the undertaking of this work would clearly have benefited from a larger population sample. The difficulties associated with finding and maintaining appropriate subjects for clinical trails is recognised as a ubiquitous problem for researchers, especially for those working in neurological rehabilitation. Often, this is an important factor for implementation of multi-centre trials. Clearly, the recruitment of stroke sufferers, who are often elderly people with ongoing poor health, involves some unique difficulties.

It is notable that whilst the heterogeneity of the general stroke population was unlikely to be reflected in the sample size used here, the stringent experimental criteria employed meant that the subjects studied in the balance investigations were homogeneous with respect to age and time since stroke. For those studies, all of the subjects were first time stroke sufferers and were classifiable as severely disabled. The decision to accept subjects based on the latter criterion was strengthened by ADL assessment. For the studies of gait, which formed the second major part of the research, the control group contained only three subjects. In this case, the randomized control trial philosophy was lost completely (Motulski, 1995; Anthony, 1999). Furthermore, in the gait tests, the fact that the control group sample size was much smaller than for the experimental group

meant that the mean age of group was 10 years younger than for the experimental group, although the time since stroke for both groups was similar. In the control group, 90 % of subjects had left side paresis, whereas the number of subjects with a left or right side in the experimental group paresis was equal. These factors are probably the most serious limitations of the present studies. It is emphasised that the statistical power of all of the studies reported here may be insufficient to detect potentially small and possibly important changes resulting from orthotic intervention. The statistical treatment of the data may have lead to type II errors (Anthony, 1999; Sim and Reid, 1999).

2. The finding that motions occurring in the frontal and transverse planes were not sufficiently reliable or repeatable meant that the kinematic gait analysis was limited to two dimensions (saggital plane). Consequently, it can be argued that incomplete information concerning the kinematics of human gait was available, as differences were found between 3-D and 2-D gait analyses of the lower limbs. It is well established that the goal of locomotion is to generate movements, which propel the body forward and that the major motion of lower limb movements is performed in the plane of progression. However, analysis of the saggital plane provides only partial information as, for example, the action of the hip abductors can only be observed in the frontal plane, and interpreting knee movement requires that motions in the frontal plane are specified during stance (abduction) and swing (adduction) phases. Although ankle motions are executed predominantly in the saggital plane, information for this joint can also be derived in the transverse (rotation) and frontal planes (internal/external).

3. Subjects' balance was tested using a single force plate, with subjects positioned in a standard manner. The rationale for this approach was that, in theory, it enabled comparable challenge of balance control systems between groups, and therefore equivalent monitoring of static standing. There are, however, limitations in the amount of information gained by this means (Winter *et al.*, 1996). It has been argued that at least

two force plates are required in order to adequately assess balance control and any effects on asymmetric standing position when the subject's weight bears mostly over the unaffected leg (Davidson and Waters, 2000).

4. Another limitation of this work was that the effects of DAFOs were evaluated solely with spatio-temporal and kinematic assessments, without consideration of kinetic gait parameters. The parameters studied are generally accepted as adequate for the evaluation of several gait pattern characteristics. However, in the absence of force measurements during foot contact and assessment of kinetic parameters (particularly the mechanical power or work) it cannot be assumed that data concerning the effects of DAFOs reflect functional roles of musculature at the anatomic (cellular) level, i.e. as muscle fibres shorten or lengthen under tension. In the present setting, the small physical size of the force plate apparatus made it difficult for some subjects to use as they sometimes experienced foot positioning problems in the correct (central) region of the walkway at the correct time, due to short step lengths.

5. A further possible concern is that the gait data reported here describe subjects' gait performance in a controlled laboratory environment, which, at best, only approximates mobility in every day life. Furthermore, the walking tests were limited to straight line walking in the central region of walkway. By this method, no account is possible of the variety and complexity of walking patterns (such as turning and bending), which the patient must execute as part of day-today living within their home.

6. A potential source of error concerns the daily lengths of time for which patients used their splint. Patient feedback on the overall time the device was used was collected by questionnaire after each test. However, the precise duration of time when the splint was used for active movements was unknown; some of the subjects in the experimental group may have used the DAFOs only for short (hourly) periods. Finally, it should be noted that all of the subjects wore their own (comfortable) shoes on the unaffected side by stroke. It

is unknown whether the findings of the present studies were influenced by differences in this footwear.

5 GENERAL DISCUSSION AND CONCLUSIONS AND FUTURE STUDIES

5.1 General discussion

Recovery of an individual's walking function in the home environment is regarded as the most important goal following stroke. Gait rehabilitation involving orthoses is a means by which this improved mobility may be achieved. Orthotic intervention may be efficacious in affecting change by reducing impairment, disability and handicap, or by slowing the deterioration post stroke. The DAFO is a novel type of ankle-foot orthosis that exploits developments in fabrication techniques using more flexible materials and light construction. It is theorised that this device may promote gait recovery after stroke via biomechanical and neurophysiological mechanisms. However, information on the potential benefits of the DAFO is sparse, with earlier research consisting of mostly single case studies, and an individual focus on patients' standing balance and gait. This thesis describes the results of detailed studies on the effects of DAFOs on stroke patients' balance control and gait performance using modern quantitative and qualitative methods and, to the best of the author's knowledge, provides the most comprehensive assessment of this appliance to date.

It was proposed that DAFOs alter motor behaviour after stroke involving the acquisition of standing balance (Hypothesis I) and gait (Hypothesis II) performance. It was predicted that any such alterations would be reflected by positive subjective opinions given by stroke patients (Hypothesis III). Proof of these working hypotheses would be useful in the implementation of increased DAFO usage in rehabilitation management strategies in the UK. Overall, various interpretations of the results of the balance and gait investigations provided no consistent and straightforward evidence to support Hypotheses I and II. Thus, none of the balance parameters studied appeared to be altered appreciably by DAFO use over the duration of the testing trials, compared to when subjects wore their own casual shoes. In this case, none of the data comparisons

yielded outcomes that achieved statistical significance. In addition, overall, the gait parameters did not demonstrate the benefits of DAFOs. Thus, these Hypotheses should be rejected and the Null hypothesis accepted; that there is no difference in stroke subjects' standing balance and gait when DAFOs are used compared to shoes alone.

Whilst the quantitative findings of this research project do not strongly support the idea that DAFOs improve standing balance and gait performance mechanically or via neurophysiological action, stroke patients' opinion of DAFOs clearly showed evidence of the opposite view. Very positive feedback of subjects' experiences when using the splint during daily activity over a three-month follow-up period was obtained. These subjects expressed confidence in the splint, which they perceived as being very beneficial to their walking ability in everyday life at home. Particularly, DAFOs seems to improve their confidence to carry out daily physical functions both inside and outside the home, which perhaps provides the strongest evidence to support the use of orthoses in the rehabilitation of stroke patients. Further, subjects' opinion of the orthosis seems to improve over the 12 weeks research time. However, as a consequence of an unfortunate limitation of the testing methods (the use of a non-validated questionnaire), Hypothesis III had to be rejected. Nevertheless, clearly this study demonstrated that more work is needed to improve the quality and convenience of DAFO use in everyday life.

This present research endeavours are unique in that they are the first to; 1) measure randomised groups of stroke subjects, with and without DAFOs; 2) use comprehensive gait analysis methods to obtain detailed information on the balance and gait performance of stroke patients; 3) identify a number of gait and balance parameters that are potentially sensitive to DAFO use; and 4) collect details of subjects' own experience of DAFO use. Thus, the work lead to the identification of several novel findings. It was found that, in general, when randomised group results were compared, using DAFOs instead of shoes did not lead to statistically significant changes in the gait

or balance characteristics of stroke subjects. However, within-group comparisons revealed changes in some parameters, which are consistent with improved gait performance related to DAFO use. Subjects' opinion of DAFOs when walking provided further support that the device may be efficacious, with 80% of users indicating that they perceived the splint to be useful during walking and in every day life.

Whilst the balance studies clearly failed to provide statistically relevant data in support of the possible benefits associated with DAFO use during quiet standing compared to shoes only, the findings of these studies does provide several new and interesting observations for potential effects of the device on some parameters of standing balance control. Thus, it was shown that the device could provide some improvement, especially in relation to the lateral sway velocity and variability (Fsd) of the spectral frequency (in a-p and lat directions) parameters. It is possible that such effects are achieved, at least in part, due to the mechanical support provided by the low construction of the orthosis, which still affords considerable support for the ankle over the malleollus, and enables the subject to place the foot on the floor more confidently. The finding that these effects were also discernable when subjects were tested in an eyes-closed condition, make it tempting to speculate that a component of a DAFO-mediated influence may indeed involve altered somato-sensory system responses (via joint afferent neurons and muscle receptors under the foot and ankle), such that the postural control system may facilitate balance capacity, as was proposed earlier (Hylton, 1990). However, because of the limitations of the present studies already described, these ideas, at present, must remain conjecture. Clearly, verification of these proposals will require further investigation.

The results obtained for the gait measures were more difficult to interpret in terms of statistical relevance. In some cases, specific gait variables did appear to be altered in such a way as to suggest that the device was efficacious within the experimental group. The finding that gait velocity, stride length, single stance duration, and the maximum

foot velocity value in the middle of the swing phase parameters were all improved with DAFOs compared to shoes, and the fact that the magnitude of the differences recorded when subjects wore the DAFO as opposed to shoes alone did achieve statistical significance, may indicate that the DAFO alters these gait parameters towards a more normal level compared to shoe use. However, it was argued that it was unlikely that the demonstration of potentially useful actions of the device on one or more gait variables can be assumed to reflect a genuine and fundamental improvement in stroke patients' gait performance, as it is unknown whether any single or combination of gait variables can be used to describe human gait entirely. Stroke patients walking difficulties are mainly characterised by a slow gait velocity (Manchester *et al.*, 1989; Witte and Carlsson, 1997). Problems occur particularly during late stance and swing phases, when gait velocity is particularly slow, which is thought to be most likely due to poor muscle strength, and the combination of several neurological factors with these patients, as described in the Introduction to this thesis (De Quervain *et al.*, 1996; Wooley, 2001; Kwakkel and Wagenaar, 2002). The current studies made detailed assessments of stroke subjects' gait difficulties, and some of the findings clearly support earlier theories, suggesting that the beneficial effects of DAFOs result not only from their direct action on the alignment of the joints of the ankle-foot complex, but also from the consequential effects of this on the alignment of more proximal joints and therefore the magnitudes of the external moments acting on them (Bowker, 1993). The possibility of DAFOs having positive effects on the motion of the shank was also noted in this study, with better values recorded with the DAFOs for the foot and shank motions at the end of stance and early swing phase of the gait cycle.

Earlier studies have suggested that DAFOs might have a greater impact with more severely disabled subjects, for whom the observation of improvements may be more apparent (Wolley *et al.*, 1996; Wooley, 2001). The present work, which studied subjects who were all classified as severely disabled, supports this idea. Thus, whilst it was

found that the group consisting of relatively 'slow' walkers group provided mostly negative gait results, the gait tests for the 'fast' walkers yielded encouraging results, which, if proven, would indeed suggest that disability levels might influence the extent of DAFO mediated effects. Whether such clear-cut distinctions in relation to disability and likely benefit associated with DAFO use can be made awaits further investigation. It will be of interest to determine whether the potential for such benefits is entirely a function of the extent of the initial lesion, or is more complex involving other factors, such as motor relearning and the subjects' physical activity levels (Wulf *et al.*, 2003). Wulf and colleagues (2003) used brain imaging techniques to establish that the gaining of skills by stroke subjects in every day life (such as walking, standing, reaching etc.) depends on the active participation of the learner. An important factor for enhancing the effectiveness of training is direction of the patient's attention focus. In the case of the present studies, it is a possibility that active use of the DAFO helps to focus the patient's attention and awareness of their gait pattern, which may be beneficial (Wulf *et al.*, 2003).

Another interesting finding was that most gait improvements, which were likely to be attributable to DAFO use, were achieved at the beginning of the research trials, with no obvious further benefits in the later tests, with the exception of gait velocity, which was also clearly improved after four weeks. It is doubtful that these effects can be attributed to natural recovery. Thus, the potential of introducing artefacts due to this factor was made less likely by the method of mean difference measurement statistics, which was used to compare individual differences of DAFO minus shoe measures within the experimental group tests. However, the large variability of the CI levels for these measures means that the apparent existence of these positive effects remains inconclusive. Clarification of this proposal would benefit from further studies involving active, functional tests (described later). Clearly, resolution of these issues would be of considerable clinical importance in relation to stroke patient rehabilitation.

It was suggested that acceptance of Hypothesis III would require that evidence was gained for at least one of the other two hypotheses. This assumption is debatable, because the questionnaires used in the testing of hypothesis III did not involve validated scales. Nonetheless, it is proposed that, for the whole research described in this thesis, the data collected for these studies are most informative, and provide the clearest insight concerning the potential for beneficial effects of the DAFO. The results of these findings provide important evidence for potentially beneficial effects of the DAFOs for this group of stroke subjects, and are supported by earlier subjective feedback investigations that used single case designs. Dieli *et.al.* (1997) assessed DAFO use in a single-case study and found that users were "pleased" with the low and custom-made design, which helped their equinovarus foot position. In a more recent study, Tyson *et al.* (2001) reported positive feedback from users of the Hinged Ankle-Foot Orthosis. It is notable that in this study many subjects felt that the hinged orthosis was too heavy. In the present studies, the design of the DAFO meant that its weight was not a significant factor. Overall, this work confirms and greatly extends these earlier investigations. The possibility that DAFOs might form a useful adjunct for these stroke patients' rehabilitation cannot be excluded, and merits further investigation.

The scientific study of subjects with neurological deficit is a difficult area. The individual nature and severity of the initial insult and the widely varying patterns of disability and recovery make comparisons between experimental and control groups difficult. Based on the results of the studies undertaken for this research, and the failure to demonstrate consistent statistically significant differences, the working hypotheses proposed are rejected. However, this conclusion is provisional. The fact that the studies used only a limited number of experimental subjects, and may have been subject to type II error cannot be ignored. As already indicated, a concern was that the present studies used groups that contained too few subjects and therefore that the experiments lacked statistical power. Indeed, this research reports data (particularly in the gait studies

section) which often had high CI limits, which suggests that the findings most certainly cannot be generalised or extrapolated in terms of the entire stroke population. However, these findings do indicate clearly positive effects of DAFO use for some of these experimental subjects.

The detailed description of DAFO provision that has been presented (section 2.2.2) and Appendix II demonstrates that the use of these orthoses always relies on the work of a highly professional team, and that the cost of these splints could therefore be questioned. Very recent studies have demonstrated, however, that the use and cost of assistive devices with stroke patients during the first year comprises a small fraction of the total costs for care and rehabilitation (Gosman-Hedström *et al.*, 2002). Although, further evaluation is needed in the field of cost effectiveness, the research here provides evidence that DAFO use over a longer period of time may improve patients' daily functions and therefore could lower the total costs of their health care.

Orthoses have been a part of stroke patients' rehabilitation now for a long time but their usefulness continues to be questioned, particularly the extent to which they engender normal movements. Their use is very often abandoned without strong evidence of positive effects (Lennon *et al.*, 2001). The current research clearly indicates that further work is needed to assess the effects of DAFO use. In addition, this study identified some parameters of balance and gait, which might be more useful to use in further studies. The new proposal that there may be uncontrolled variables within either the patient group or in the DAFOs (or both) which mean that some DAFOs work better than other, suggests that a priority task is to identify what these variables are so they can be controlled in future studies. Of course, if these variables are related to the precise nature of the neurological impairment, this would be extremely difficult to do (given the difficulties in this study generating a suitable experimental group).

The fact that patients' opinions demonstrated that DAFOs can improve functional skills in daily life, raises the important question as whether or not improved quality of

movements translates directly into improved functional skills and physical activity. Stroke rehabilitation aims to improve patients' active, functional life at home. Therefore, more functional and dynamic assessments of daily activities would be helpful in the evaluation of DAFOs. Some examples of this approach to rehabilitation research with stroke patients, unrelating to DAFOs, have already been published (Nadeau *et al.*, 1999a; Thomas *et al.*, 2002; Leung and Moseley, 2003).

The nature of the neurophysiological response to an orthotic device is understood only in the broadest terms. That such a beneficial response is possible has been demonstrated, but the features that are necessary within the orthoses to elicit any particular neurophysiological effect are understood only in the most general way. It is therefore perhaps not surprising that functional responses of the stroke patients to DAFOs was highly variably, as it is reasonable to suppose that in some individual DAFOs the critical design features were present, and in other they were not. Clearly this is an area which requires considerably more study.

5.2 Conclusions

1. This research failed overall to demonstrate a significant effect of DAFOs on the rehabilitation of stroke patients, but presents clear indications that further study is justified.

2. The main findings verified that DAFO use does not alter standing balance when two groups of stroke subjects were compared.

3. Anecdotal evidence was obtained which suggest that DAFOs may have potential to improve certain aspects of standing balance, particularly the lateral velocity of sway and variability of spectral frequency parameters.

4. There were no consistent and statistically significant differences in the subjects' gait performance between the groups using DAFOs and shoes-only.

5. The study established that using a DAFO on the affected leg of a stroke patient did not alter the gait pattern on their unaffected side.

6. Within the experimental subjects, positive ($p < 0.05$) effects of using DAFOs were evident for some gait parameters such as gait velocity, stride length, single stance phase duration and maximum foot velocity in the middle of swing phase compared to shoes use.

7. Extremely optimistic and constructive user feedback for the DAFO was obtained, providing strong support for the idea that these splints may provide benefit by improving physical function for some stroke patients.

5.3 Future studies

The present research illustrates the feasibility of running a clinical trial for non-acute state stroke patients using DAFOs and provides a useful framework for future investigations of this, and possibly other types of orthosis. Further randomised studies of the effects of DAFO use in stroke patients' rehabilitation should firstly address the limitations as specified in section 4. Clearly, large sample numbers would be generated by multi-centre recruitment (which, for practical reasons, was beyond the scope of the present research) involving larger geographical areas and several NHS Trusts. In order to provide more comparable subject groups, it would be useful to introduce pre-review assessments, before randomisation. A more detailed picture of the actual time a subject spends wearing their DAFO actively could be obtained by more regular follow-up questionnaires, via home visits, or personal entries made in the subject's own diary.

The variability of results within stroke subjects also suggests that it is very likely that DAFOs are only indicated and beneficial for some subjects. This emphases the need for future investigations to be carried out more carefully and systematically, as the information gained could identify which types of patients would benefit from having DAFOs. Until we understand the intricacies of the interaction between orthotic design variables and impaired neurophysiology, it will be difficult to optimise the prescription for different individuals. But it is important to be aware meantime that small changes in the design of DAFOs may lead to major differences in functional outcomes and, further, that these outcomes may differ significantly between individuals.

Browne and O'Hare (2000) have addressed the issue of force platform reliability. These authors have commented on the lack of comprehensive calibration procedures used in gait laboratories, which casts doubt on the results obtained with these systems. Following work on prototype force platform apparatus, they propose quality control procedures involving testing of specific sources of error, how the tests should be performed and recommendations for the frequency with which they can be carried out.

The authors advise that the following factors be monitored: linearity, hysteresis, noise, repeatability, system drift, temporal stability, spatial accuracy, uniformity and frequency responses. Future work may determine a baseline of time intervals for performing these calibrations using force platforms of varying ages and complexity (Browne and O'Hare, 2000). Adoption of such systematic quality control procedures will undoubtedly enable more useful comparisons of data collected within and between laboratories studying human balance.

Further knowledge of the influence of DAFOs on subjects' ambulation could be gained by extending studies to include data collection of more complex movements, such as turning, sit-to-stand or ascending/descending stairs. Three-dimensional gait analysis systems such as APAS™ are portable and adaptable and, theoretically, the instrumentation could be tailored to almost any testing environment, perhaps in the form of a generalised home setting, which better approximates typical day-to-day living. Future work should also address the longer-term effects of DAFO use, and the differences between different splint designs, to determine which are more effective for specific gait difficulties with stroke subjects, whilst retaining cost-effectiveness.

Studies of the type reported here are restricted in that DAFO effects at the physiological level of muscle function are undefined. Complementary work that combines electromyographic (EMG) information with 3-D kinematic and kinetic data would undoubtedly provide a more complete picture of these interrelated processes in relation to stroke patients' gait, and the influence of DAFO intervention. This, supplemented by the evaluation of subjective feedback of orthoses by using validated scales, may also increases our understanding of the mechanisms underlying gait disturbance and its correction.

The sophisticated gait assessment approaches outlined above will be aided by the current availability of rapidly improving PC technology, together with new advances in gait analysis software. More efficient computer technology has obvious benefits for

clinical studies. It is notable that since the inception of the present studies, PC data storage capacity and clock processing speeds have increased greatly, whereas their cost has reduced. It is hoped that studies such as these will provide further objective knowledge on the usefulness of DAFO intervention, and add to the value of rehabilitation not only by refining the rehabilitation technique itself, but also in terms of improved psychosocial and cost effectiveness, which ultimately form important components of progress leading to a better clinical outcome for individuals affected by stroke.

6 REFERENCES

Adams, S.A. (1995) The Rivermead motor assessment. In: *Physiotherapy in Stroke Management.* pp. 125-138. Edited by Harrison, M.A., Churchill Livingstone, Edinburgh.

Aisen, M.L. (1992) *Orthotics in Neurologic Rehabilitation.* pp. 56-59 Domos Publications, New York.

Allard, P., Lachance, R., Aissaoui, R., and Duhamel, A. (1996) Simultaneous bilateral 3-D able-bodied gait. *Human Movement Science* **15**, 327-346.

Allum, J. H., Bloem, B. R., Carpenter, M. G., Hulliger, M., and Hadders-Algra, M. (1998) Proprioceptive control of posture: a review of new concepts. *Gait Posture* **8**, 214-242.

Angulo-Kinzler, R. M., Mynark, R. G., and Koceja, D. M. (1998) Soleus H-reflex gain in elderly and young adults: modulation due to body position. *J. Gerontol. A Biol. Sci Med. Sci* **53**, M120-M125.

Anthony, D. (1999) *Understanding Advanced Statistics. A Guide for Nurses and Health Care Researchers*, Churchill Livingstone, New York.

Apkarian, J., Naumann, S., and Cairns, B. (1989) A three-dimensional kinematic and dynamic model of the lower limb. *J. Biomech.* **22**, 143-155.

Ashburn, A. (1995) A review of current physiotherapy in the management of stroke. In: *Physiotherapy in Stroke Management*, pp. 3-22. Edited by Harrison, M.A., Edinburgh.

Ashburn, A., Partridge, C., and De Souza, L. (1993) Physiotherapy in the rehabilitation of stroke: a review. *Clinical Rehabilitation* **7**, 337-345.

Bach-y-Rita, P. (1981) Brain plasticity as a basis of the development of rehabilitation procedures for hemiplegia. *Scand. J. Rehabil. Med.* **13**, 73-83.

Bach-y-Rita, P. (1990) Brain plasticity as a basis for recovery of function in humans. *Neuropsychologia.* **28**, 547-554.

Baer, G., and Smith, M. (2001) The recovery of walking ability and subclassification of stroke. *Physiother. Res. Int.* **6**, 135-144.

Bamford, J., Sandercock, P., Dennis, M., Warlow, C., Jones, L., McPherson, K., Vessey, M., Fowler, G., Molyneux, A., and Hughes, T. (1988) A prospective study of acute cerebrovascular disease in the community: the Oxfordshire Community Stroke Project 1981-86. 1. Methodology, demography and incident cases of first-ever stroke. *J. Neurol. Neurosurg. Psychiatry* **51**, 1373-1380.

Bartlett, R. (1997a) Movement (kinematic) considerations. In: *Introduction to Sports Biomechanics*, pp. 47-81. Edited by Bartlett, R., E & FN Spon, London.

Bartlett, R. (1997b) Other techniques for the analysis of sports movements. In: *Introduction to Sports Biomechanics*, pp. 254-281. Edited by Bartlett, R., E & FN Spon, London.

Beckerman, H., Becher, J., Lankhorst, G. J., and Verbeek, A. L. (1996) Walking ability of stroke patients: efficacy of tibial nerve blocking and a polypropylene ankle-foot orthosis. *Arch. Phys. Med. Rehabil.* **77**, 1144-1151.

Berg, K. (1989) Balance and its measure in the elderly: a review. *Physiother. Can.* **41**, 240-245.

Bhakta, B. B., and Bamford, J. M. (2002) Botulinum toxin for spasticity after stroke or non-progressive brain lesion. *The Cochrane Database of Systematic Reviews* **1**, 1-5.

Bittigau, P., and Ikonomidou, C. (1997) Glutamate in neurologic diseases. *J. Child Neurol.* **12**, 471-485.

Blaszczyk, J. W., Hansen, P. D., and Lowe, D. L. (1993) Evaluation of the postural stability in man: movement and posture interaction. *Acta Neurobiol. Exp.* **53**, 155-160.

Blaszczyk, J. W., Prince, F., Raiche, M., and Hebert, R. (2000) Effect of ageing and vision on limb load asymmetry during quiet stance. *J. Biomech.* **33**, 1243-1248.

Bobath, B. (1990) *Adult Hemiplegia: Evaluation and Treatment*, 3rd Ed., Butterworth-Heinemann, Oxford.

Bohannon, R. W. (1997) Comfortable and maximum walking speed of adults aged 20-79 years: reference values and determinants. *Age Ageing* 26, 15-19.

Bohannon, R. W., Horton, M. G., and Wikholm, J. B. (1991) Importance of four variables of walking to patients with stroke. *Int. J. Rehabil. Res.* 14, 246-250.

Bohannon, R. W., Tiberio, D., and Zito, M. (1989) Selected measures of ankle dorsiflexion range of motion: differences and intercorrelations. *Foot Ankle* 10, 99-103.

Bohannon, R. W., Walsh, S., and Joseph, M. C. (1993) Ordinal and timed balance measurements: reliability and validity with patients with stroke. *Clin. Rehabil.* 7, 9-13.

Bonita, R., and Beaglehole, R. (1988) Recovery of motor function after stroke. *Stroke* 19, 1497-1500.

Bonita, R. and Beaglehole, R. (1991) Stroke mortality. In: *Stroke: Population, Cohorts and Clinical Trials*, Edited by Whisnant, J.P., Butterworth Heinemann, Oxford.

Bonita, R., Beaglehole, R., and North, J. D. (1984) Event, incidence and case fatality rates of cerebrovascular disease in Auckland, New Zealand. *Am. J. Epidemiol.* 120, 236-243.

Borghese, N. A., and Ferrigno, G. (1990) An algorithm for 3-D automatic movement detection by means of standard TV cameras. *IEEE Trans. Biomed. Eng.* 37, 1221-1225.

Bowker, P. (1993) The biomechanics of orthosis. In: *Biomechanical Basis of Orthotic Management*, pp. 38-57. Edited by Bowker, P., Bader, D., Condie, D.N., Pratt, D.J., and Wallace, W.A., Butterworth-Heinemann, Oxford.

Bowling, A. C., and Beal, M. F. (1995) Bioenergetic and oxidative stress in neurodegenerative diseases. *Life Sci.* 56, 1151-1171.

Briggs, R. C., Gossman, M. R., Birch, R., Drews, J. E., and Shaddeau, S. A. (1989) Balance performance among noninstitutionalized elderly women. *Phys. Ther.* 69, 748-756.

Browne, J. and O'Hare, N. (2000) A quantitative control procedure for force platforms. *Physiol. Meas.* 21, 515-524.

Browne, J. E., and O'Hare, N. J. (2001) Review of the different methods for assessing standing balance. *Physiotherapy* **87**, 489-495.

Brust, J.C.M. (1991) Cerebral circulation: stroke. In: *Principles of Neural Science*, 3rd Ed., Edited by Kandell,E.R., Schwartz,J.H., and Jessell,T.M. , Elsevier, New York.

Burdett, R. G., Borello-France, D. , Blatchly, C., and Potter, C. (1988) Gait comparison of subjects with hemiplegia walking unbraced, with ankle-foot orthosis, and with air-stirrup brace. *Phys. Ther.* **68**, 1197-1203.

Burnfield, J. M., Josephson, K. R. , Powers, C. M., and Rubenstein, L. Z. (2000) The influence of lower extremity joint torque on gait characteristics in elderly men. *Arch. Phys. Med. Rehabil.* **81**, 1153-1157.

Burridge, J. H., Wood, D. E., Taylor, P. N., and McLellan, D. L. (2001) Indices to describe different muscle activation patterns, identified during treadmill walking, in people with spastic drop-foot. *Med. Eng Phys.* **23**, 427-434.

Butler, P. B., Farmer, S. E., and Major, R. E. (1997) Improvement in gait parameters following late intervention in traumatic brain injury: a long-term follow-up report of a single case. *Clin. Rehabil.* **11**, 220-226.

Carr, J. and Shepherd, R. (1998a) *Neurological Rehabilitation*, pp. 222-241, Butterworth-Heinemann, Oxford.

Carr, J. and Shepherd, R. (1998b) Stroke. In: *Neurological Rehabilitation*, pp. 242-278. Edited by Carr, J. and Shepherd, R., Butterworth Heinemann, Oxford.

Carr, J. and Shepherd, R. (2003) *Stroke Rehabilitation: Guidelines for exercise and Training to Optimize Motor Skill*, Butterworth-Heinemann, London.

Chaudhuri, S., and Aruin, A. S. (2000) The effect of shoe lifts on static and dynamic postural control in individuals with hemiparesis. *Arch. Phys. Med. Rehabil.* **81**, 1498-1503.

Chen, C. L., Yeung, K. T., Wang, C. H., Chu, H. T., and Yeh, C. Y. (1999) Anterior ankle-foot orthosis effects on postural stability in hemiplegic patients. *Arch. Phys. Med. Rehabil.* **80**, 1587-1592.

Chin, P.J., Rosie, A., and Irving, M. (1982) Studies in hemiplegic gait. In: *Advances in Stroke Therapy*. Edited by Rose, F.C., Raven Press, New York.

Chiu, D., Krieger, D., Villar-Cordova, C., Kasner, S. E., Morgenstern, L. B., Bratina, P. L., Yatsu, F. M., and Grotta, J. C. (1998) Intravenous tissue plasminogen activator for acute ischemic stroke: feasibility, safety, and efficacy in the first year of clinical practice. *Stroke* **29**, 18-22.

Chu, T. T. (2001) Biomechanics of ankle-foot orthoses: past, present, and future. *Top. Stroke Rehabil.* **7**, 19-28.

Cohen, H. (1999) *Neuroscience for Rehabilitation*, pp. 45-281, Lippincott, Philadelphia.

Collen, F. M., Wade, D. T., and Bradshaw, C. M. (1990) Mobility after stroke: reliability of measures of impairment and disability. *Int. Disabil. Stud.* **12**, 6-9.

Condie, D.N. and Meadows, C.B. (1993) Ankle-foot orthosis. In: *Biomechanical Basis of Orthotic Management*, pp. 99-123. Edited by Bowker, P., Bader, D., Condie, D.N., Pratt, D.J., and Wallace, W.A., Butterworth-Heinemann, Oxford.

Condie, E. and Condie, D.N. (1995) Orthotic Management of stroke patients. In: *Physiotherapy in Stroke Management*, Edited by Harrison, M.A., Churchill Livingstone, Edinburgh.

Corr, S., and Bayer, A. (1992) Poor functional status of stroke patients after hospital discharge. *British Journal of Occupational Therapy* **55**, 383-385.

Craik, R. L. and Dutterer, L. (1995) Spatial and temporal characteristics of footfall patterns. In: Gait Analysis. Theory and Applications, pp. 143-158. Eds. Craik, R. L. and Oatis, C. A. Mosby, St. Louis.

Crenshaw, S., Herzog, R., Castagno, P., Richards, J., Miller, F., Michaloski, G., and Moran, E. (2000) The efficacy of tone-reducing features in orthotics on the gait of children with spastic diplegic cerebral palsy. *J. Pediatr. Orthop.* **20**, 210-216.

Curtis, E. (1995) Dynamic ankle-foot orthosis - tone inhibiting. *A. P. C. P. Journal* **8**, 23-30.

Cusick, B., and Sussman, M. D. (1982) Short leg casts. Their role in the management of cerebral palsy. *Physical and Occupational Therapy in Pediatrics* **2**, 93.

Dannenbaum, R. (1982) Spinal influences of cutaneous reflexes on the foot at rest and during locomotion: their possible relevence to physiotherapy. *Physiother. Can.* **34**, 139-143.

Davidson, I., and Waters, K. (2000) Physiotherapists working with stroke patients: A national survey. *Physiotherapy* **86**, 69-80.

Davies, P. (2000) *Steps to Follow*, 2nd Ed., Springer, Berlin.

De Quervain, I. A., Simon, S. R., Leurgans, S., Pease, W. S., and McAllister, D. (1996) Gait pattern in the early recovery period after stroke. *J. Bone Joint Surg. Am.* **78**, 1506-1514.

de Vries, J. (1991) Evaluation of lower leg orthosis use following cerebro-vascular accident. *Int. J. Rehabil. Res.* **14**, 239-243.

Demeurisse, G., Demol, O., and Robaye, E. (1980) Motor evaluation in vascular hemiplegia. *Eur. Neurol.* **19**, 382-389.

Department of Health. (2001) The *National Service Framework for Older People*, www.doh.gov.uk/nsf/olderpeople.htm.

Dettmann, M. A., Linder, M. T., and Sepic, S. B. (1987) Relationships among walking performance, postural stability and functional assessments of the hemiplegic patient. *Am. J. Phys. Med.* **66**, 77-90.

Diamond, M. F., and Ottenbacher, K. J. (1990) Effect of a tone-inhibiting dynamic ankle-foot orthosis on stride characteristics of an adult with hemiparesis. *Phys. Ther.* **70**, 423-430.

Dickstein, R., and Dvir, Z. (1993) Quantitative evaluation of stance balance performance in the clinic using a novel measurement device. *Physiother. Can.* **45**, 102-108.

Dieli, J., Ayyappa, E., and Hornbeak, S. (1997) Effect of Dynamic AFOs on Three Heminplegic Adults. *Journal of Prosthetics and Orthotics* **9**, 82-89.

Diener, H. C., Bacher, M., Guschlbauer, B., Thomas, C., and Dichgans, J. (1993) The coordination of posture and voluntary movement in patients with hemiparesis. *J. Neurol.* **240**, 161-167.

Dietz, V. (1992) Human neuronal control of automatic functional movements: interaction between central programs and afferent input. *Physiol. Rev.* **72**, 33-69.

Dietz, V., and Duysens, J. (2000) Significance of load receptor input during locomotion: a review. *Gait Posture* **11**, 102-110.

Dirnagl, U., Iadecola,C., and Moskowitz,M.A. (1999) Pathobiology of ischaemic stroke: an integrated view. *Trends Neurosci.* **22**, 391-397.

Dombovy, M. L. (1991) Rehabilitation and the course of the recovery after stroke. In: *Stoke: Population, Cohorts, and Clinical Trials*, Eds. Whisnant, J.P., Butterworth-Heinemann.

Drummond, A. (1990) Leisure activity after stroke. *Int. Disabil. Stud.* **12**, 157-160.

Duncan, P. W., Jorgensen, H. S., and Wade, D. T. (2000) Outcome measures in acute stroke trials: a systematic review and some recommendations to improve practice. *Stroke* **31**, 1429-1438.

Duncan, W. R., and Mott, D. H. (1983) Foot reflexes and the use of the "inhibitive cast". *Foot. Ankle.* **4**, 145-148.

Enoka, R M. (2002) Chronic adaptations. In: *Neuromechanics of Human Movement*, 3rd Ed., pp. 397-447. Edited by Enoka, R.M., Human Kinetics, Illinois.

Era, P., Schroll, M., Ytting, H., Gause-Nilsson, I., Heikkinen, E., and Steen, B. (1996) Postural balance and its sensory-motor correlates in 75-year-old men and women: a cross-national comparative study. *J. Gerontol. A Biol. Sci Med. Sci* **51**, M53-M63.

Evans, M. D., Goldie, P. A., and Hill, K. D. (1997) Systematic and random error in repeated measurements of temporal and distance parameters of gait after stroke. *Arch. Phys. Med. Rehabil.* **78**, 725-729.

Feuerbach, J. W., Grabiner, M. D., Koh, T. J., and Weiker, G. G. (1994) Effect of an ankle orthosis and ankle ligament anesthesia on ankle joint proprioception. *Am. J. Sports Med.* **22**, 223-229.

Forster, A., and Young, J. (2002) The Clinical and cost effectiveness of physiotherapy in the management of elderly people following a stroke. *CSP Stroke Care* **2**, 1-43.

Frank, J. S., and Earl, M. (1990) Coordination of posture and movement. *Clin. Rehabil.* **70**, 855-863.

Friedman, P. J. (1990) Gait recovery after hemiplegic stroke. *Int. Disabil. Stud.* **12**, 119-122.

Gaviria, M., D'Angeli, M., Chavet, P., Pelissier, J., and Peruchon, E. (1996) Plantar dynamics of hemiplegic gait: a methodological approach. *Gait Posture* **4**, 297-305.

Gefen, A. (2001) Simulations of foot stability during gait characteristic of ankle dorsiflexor weakness in the elderly. *IEEE Trans. Neural Syst. Rehabil. Eng* **9**, 333-337.

Geurts, A. C., Nienhuis, B., and Mulder, T. W. (1993) Intrasubject variability of selected force-platform parameters in the quantification of postural control. *Arch. Phys. Med. Rehabil.* **74**, 1144-1150.

Ghent, R., Probst, J., Denegar, C. R., and Clemente, F. R. (1992) Assessment of the reliability of Chattecx Balance System. *Phys. Ther.* **6** (suppl), S66.

Gilles, M., Wing, A. M., and Kirker, S. G. (1999) Lateral balance organisation in human stance in response to a random or predictable perturbation. *Exp. Brain Res.* **124**, 137-144.

Goldie, P., Evans, O. E., and Matyas, T. (1996) Performance in the stability limits test during rehabilitation following stroke. *Gait. Posture* **4**, 315-322.

Gosman-Hedström, G., Claesson, L., Blomstrand, C., and Fagerberg, B. (2002) Use and cost of assitive technology the first year after stroke: A randomized controlled trial. *Int. J. Tech. Assess. Health Care* **18**, 520-527.

Gök, H., Kucukdeveci, A., Altinkaynak, H., Yavuzer, G., and Ergin, S. (2003) Effects of ankle-foot orthoses on hemiparetic gait. *Clin. Rehabil.* **17**, 137-139.

Gresham, G. E., Duncan, P. W., and Statson, W. B. (1995) Priorities for future research. Clinical Practice Guidelines Number 16, US Department of Helath and Human Services, Agency for Health Care Policy and Research, Rockwell, Maryland. AHCPR publication no. 95-0662.

Growney, E., Meglan, D., Johnson, M., Cahalan, T., and An, K-N. (1997) Repeated measures of adult normal walking using a video tracking system. *Gait. Posture* **6**, 147-162.

Haghani, H., and Marks, R. (2000) Relationship between maximal isometric knee extensor and flexor strength of healthy men and women ages 18-74. *Physiotherapy Canada*, Winter, 33-38.

Hankey, G. J. (1999) Stroke: how large a public health problem, and how can the neurologist help? *Arch. Neurol.* **56**, 748-754.

Hansen, P. D., Woollacott, M. H., and Debu, B. (1988) Postural responses to changing task conditions. *Exp. Brain Res.* **73**, 627-636.

Harris, S. R., and Riffle, K. (1986) Effects of inhibitive ankle-foot orthoses on standing balance in a child with cerebral palsy. A single-subject design. *Phys. Ther.* **66**, 663-667.

Hayes, K. (1983) Air Stirrup bracing for patients with hemiparesis. *Clinical Management in Physiotherapy* **3**, 50.

Henon, H., Godefroy, O., Leys, D., Mounier-Vehier, F., Lucas, C., Rondepierre, P., Duhamel, A., and Pruvo, J. P. (1995) Early predictors of death and disability after acute cerebral ischemic event. *Stroke* **26**, 392-398.

Herman, B., Leyten, A. C., van Luijk, J. H., Frenken, C. W., Op, de Coul AA, and Schulte, B. P. (1982) Epidemiology of stroke in Tilburg, the Netherlands. The population-based stroke incidence register: 2. Incidence, initial clinical picture and medical care, and three-week case fatality. *Stroke* **13**, 629-634.

Herman, B., Schmitz, P. I., Leyten, A. C., van Luijk, J. H., Frenken, C. W., Op, de Coul AA, and Schulte, B. P. (1983) Multivariate logistic analysis of risk factors for stroke in Tilburg, The Netherlands. *Am. J. Epidemiol.* **118**, 514-525.

Hertanu, J. S., Demopoulos, J. T., Yang, W. C., Calhoun, W. F., and Fenigstein, H. A. (1984) Stroke rehabilitation: correlation and prognostic value of computerized tomography and sequential functional assessments. *Arch. Phys. Med. Rehabil.* **65**, 505-508.

Hesse, S., Bertelt, C., Jahnke, M. T., Schaffrin, A., Baake, P., Malezic, M., and Mauritz, K. H. (1995) Treadmill training with partial body weight support compared with physiotherapy in nonambulatory hemiparetic patients. *Stroke* **26**, 976-981.

Hesse, S., Luecke, D., Jahnke, M. T., and Mauritz, K. H. (1996) Gait function in spastic hemiparetic patients walking barefoot, with firm shoes, and with ankle-foot orthosis. *Int. J. Rehabil. Res.* **19**, 133-141.

Hesse, S., Werner, C., Matthias, K., Stephen, K., and Berteanu, M. (1999) Non-velocity-related effects of a rigid double-stopped ankle-foot orthosis on gait and lower limb muscle activity of hemiparetic subjects with an equinovarus deformity. *Stroke* **30**, 1855-1861.

Hicks, C.M. (1995) Testing hypotheses. In: *Research for Physiotherapists*, 2nd Ed., pp. 56-58. Churchill Livingstone, New York.

Hinderer, K. A., Harris, S. R., Purdy, A. H., Chew, D. E., Staheli, L. T., McLaughlin, J. F., and Jaffe, K. M. (1988) Effects of 'tone-reducing' vs. standard plaster-casts on gait improvement of children with cerebral palsy. *Dev. Med. Child Neurol.* **30**, 370-377.

Hirschberg, G. G., and Nathanson, M. (1952) Electromyographic recording of muscular activity in normal and spastic gait. *Arch. Phys. Med. Rehabil.* **33**, 217-224.

Horak, F. B., Shupert, C. L., and Mirka, A. (1989) Components of postural dyscontrol in the elderly: a review. *Neurobiol. Aging* **10**, 727-738.

Hylton, N. (1990) Dynamic casting and orthotics. In: *The Practical Management of Spasticity in Children and Adults*, Eds. Glen, M.B. and Whyte, J., Lea and Febiger, Philadelphia.

Hyndman, D., Ashburn, A., and Stack, E. (2002) Fall events among people with stroke living in the community: circumstances of falls and characteristics of fallers. *Arch. Phys. Med. Rehabil.* **83**, 165-170.

Inglin, B., and Woollacott, M. (1988) Age-related changes in anticipatory postural adjustments associated with arm movements. *J. Gerontol.* **43**, M105-M113.

Jain, M., Shrader, J., and Siegel, K. (1995) Treatment of an adult patient with dystonia using a foot orthosis with tone-inhibiting features and shoes modification. *World Conference of Physical Therapy, Washington*, PO-SI-0315-T.

Johansson, B. B. (2000) Brain plasticity and stroke rehabilitation. The Willis lecture. *Stroke* **31**, 223-230.

Jones, K. and Barker, K. (1996) *Human Movement Explained*, Butterworth-Heinemann, Oxford.

Jongbloed, L. (1986) Prediction of function after stroke: a critical review. *Stroke* **17**, 765-776.

Jorgensen, H. S., Nakayama, H., Raaschou, H. O., and Olsen, T. S. (1995) Recovery of walking function in stroke patients: the Copenhagen Stroke Study. *Arch. Phys. Med. Rehabil.* **76**, 27-32.

Jorgensen, L., Engstad, T., and Jacobsen, B. K. (2002) Higher incidence of falls in long-term stroke survivors than in population controls: depressive symptoms predict falls after stroke. *Stroke* **33**, 542-547.

Judge, J. O., Davis, R. B., and Õunpuu, S. (1996) Step length reductions in advanced age: the role of ankle and hip kinetics. *J. Gerontol. A. Biol. Sci. Med. Sci.* **51**, M303-M312.

Kadaba, M. P., Ramakrishnan, H. K., and Wootten, M. E. (1990) Measurement of lower extremity kinematics during level walking. *J. Orthop. Res.* **8**, 383-392.

Kandell, E.R., Schwartz, J.H., and Jessell,T.M. (1991) *Principles of Neural Science*, 3rd Ed., pp. 530-679, Elsevier, New York.

Karlsson, A., and Frykberg, G. (2000) Correlations between force plate measures for assessment of balance. *Clin. Biomech.* **15**, 365-369.

Kaste, M., Palomaki, H., and Sarna, S. (1995) Where and how should elderly stroke patients be treated? A randomized trial. *Stroke* **26**, 249-253.

Kaste, M., Thomassen, L., Grond, M., Hacke, W., Holtas, S., Lindley, R. I., Roine, R., Gunnar, Wahlgren N., and Wardlaw, J. M. (2001) Thrombolysis for acute ischemic stroke: a consensus statement of the 3rd Karolinska Stroke Update, October 30-31, 2000. *Stroke* **32**, 2717-2718.

Kauhanen, M. L., Korpelainen, J. T., Hiltunen, P., Nieminen, P., Sotaniemi, K. A., and Myllyla, V. V. (2000) Domains and determinants of quality of life after stroke caused by brain infarction. *Arch. Phys. Med. Rehabil.* **81**, 1541-1546.

Kejonen, P., and Kauranen, K. (2002) Reliability and validity of standing balance measurements with a motion analysis system. *Physiotherapy* **88**, 25-32.

Kettle, M., and Chamberland, M. A. (1989) The stroke patient in an urban environment. *Clinical Rehabilitation* **3**, 131-138.

Kinney LaPier, T. L., Liddle, S., and Bain, C. (1997) A comparison of static and dynamic standing balance in older men versus women. *Physiother. Can.* **2**, 207-213.

Kirker, S. G., Jenner, J. R., Simpson, D. S., and Wing, A. M. (2000) Changing patterns of postural hip muscle activity during recovery from stroke. *Clin. Rehabil.* **14**, 618-626.

Klein, P. J., and DeHaven, J. J. (1995) Accuracy of three-dimensional linear and angular estimates obtained with the Ariel Performance Analysis System. *Arch. Phys. Med. Rehabil.* **76**, 183-189.

Knutsson, E., and Richards, C. (1979) Different types of disturbed motor control in gait of hemiparetic patients. *Brain* **102**, 405-430.

Koff, D. (1995) Joint kinematics: camera-based systems. In: *Gait Analysis. Theory and Application*, Eds. Craik, R.L. and Oatis,C.A., Mosby, St. Louis.

Kojima, S., Omura, T., Wakamatsu, W., Kishi, M., Yamazaki, T., Iida, M., and Komachi, Y. (1990) Prognosis and disability of stroke patients after 5 years in Akita, Japan. *Stroke* **21**, 72-77.

Kuoppamaki-Herzig, M., and Kalbe, U. (1995) Dynaminsche fussorthesen nach Nancy Hylton. *Krankengymnastik* **47**, 795-803.

Kwakkel, G., Kollen, B. J., and Wagenaar, R. C. (1999) Therapy impact on functional recovery in stroke rehabilitation: a critical review of the literature. *Physiotherapy* **85**, 377-391.

Kwakkel, G., and Wagenaar, R. C. (2002) Effect of duration of upper- and lower-extremity rehabilitation sessions and walking speed on recovery of interlimb coordination in hemiplegic gait. *Phys. Ther.* **82**, 432-448.

Lamontagne, A., Malouin, F., and Richards, C. L. (2001) Locomotor-specific measure of spasticity of plantarflexor muscles after stroke. *Arch. Phys. Med. Rehabil.* **82**, 1696-1704.

Lamontagne, A., Malouin, F., Richards, C. L., and Dumas, F. (1997) Impaired viscoelastic behaviour of spastic plantarflexors during passive stretch at different velocities. *Clin. Biomech.* **12**, 508-515.

Lamontagne, A., Malouin, F., Richards, C. L., and Dumas, F. (2002) Mechanisms of disturbed motor control in ankle weakness during gait after stroke. *Gait. Posture.* **15**, 244-255.

Lee, D. N., and Lishman, J. R. (1976) Visual proprioceptive control of stance. *J. Hum. Mov. Scl* **1**, 87-95.

Lee, R. G., and van Donkelaar, P. (1995) Mechanisms underlying functional recovery following stroke. *Can. J. Neurol. Sci.* **22**, 257-263.

Lee, W. A., Deming, L., and Sahgal, V. (1988) Quantitative and clinical measures of static standing balance in hemiparetic and normal subjects. *Phys. Ther.* **68**, 970-976.

Leeds Evaluation Unit. (1992) Series on effective health care. *Stroke Rehabilitation* **2**.

Leigh-Smith, J., Wade, D. T., and Langton-Hewer, R. (1986) Services for stroke patients one year after stroke. *J. Epidemiol. Community. Health* **40**, 161-165.

Lehmann, J. F. (1979) Biomechanics of ankle-foot orthoses: prescription and design. *Arch. Phys. Med. Rehabil.* **60**, 200-207.

Lehmann, J. F. (1993) Push-off and propultion of the body in normal and abnorma gait. *Clinical Orthopaedics* **288**, 87-108.

Lehmann, J. F., Condon, S. M., de Lateur, B. J., and Price, R. (1986) Gait abnormalities in peroneal nerve paralysis and their corrections by orthoses: a biomechanical study. *Arch. Phys. Med. Rehabil.* **67**, 380-386.

Lehmann, J. F., Condon, S. M., Price, R., and DeLateur, B. J. (1987) Gait abnormalities in hemiplegia: their correction by ankle-foot orthoses. *Arch. Phys. Med. Rehabil.* **68**, 763-771.

Lehmann, J. F., Warren, C. G., and DeLateur, B. J. (1970) A biomechanical evaluation of knee stability in below knee braces. *Arch. Phys. Med. Rehabil.* **51**, 688-695.

Lennon, S. (2001) Gait re-education based on the Bobath concept in two patients with hemiplegia following stroke. *Phys. Ther.* **81**, 924-935.

Lennon, S., Baxter, D., and Ashburn, A. (2001) Physiotherapy based on the Bobath concept in stroke rehabilitation: a survey within the UK. *Disabil. Rehabil.* **23**, 254-262.

Leonard, C.T. (1995) The neurophysiology of human locomotion. In: *Gait Analysis: Theory and Application*, 1st Ed., pp. 46-64. Eds. Craik,R.L. and Oatis,C.A., Mosby, Missouri.

Leung, J., and Moseley, A. (2003) Impact of ankle-foot orthoses on gait and leg muscle activity in adults with hemiplegia: systematic literature review. *Physiotherapy* **89**, 39-55.

Levine, D., Whittle, M. W., Beach, J. A., and Ollard, P. G. (1996) Test-retest reliability of the Chattecx Balance System in the patient with hemiplegia. *J. Rehabil. Res. Dev.* **33**, 36-44.

Lin, S. I., and Woollacott, M. H. (2002) Postural muscle responses following changing balance threats in young, stable older, and unstable older adults. *J. Mot. Behav.* **34**, 37-44.

Lincoln, N. B., Husbands, S., Trescoli, C., Drummond, A. E., Gladman, J. R., and Berman, P. (2000) Five year follow up of a randomised controlled trial of a stroke rehabilitation unit. *BMJ* **320**, 549.

Lincoln, N. B., Jackson, J. M., Edmans, J. A., Walker, M. F., Farrow, V. M., Latham, A., and Coombes, K. (1990) The accuracy of predictions about progress of patients on a stroke unit. *J. Neurol. Neurosurg. Psychiatry* **53**, 972-975.

Lincoln, N. B., and Leadbitter, D. (1979) Assessment of motor function in stroke patients. *Physiotherapy* **65**, 61-63.

Lindley, R. I., Amayo, E. O., Marshall, J., Sandercock, P. A., Dennis, M., and Warlow, C. P. (1995) Acute stroke treatment in UK hospitals: the Stroke Association survey of consultant opinion. *J. R. Coll. Physicians. Lond.* **29**, 479-484.

Lipton, S. A. (1993) Prospects for clinically tolerated NMDA antagonists: open-channel blockers and alternative redox states of nitric oxide. *Trends. Neurosci.* **16**, 527-532.

Liu, S. H., and Lawson, D. (1995) Power spectrum of the fast Fourier transform for measurement of standing balance. *Aust. J. Sci Med. Sport* **27**, 62-67.

Lord, S. R., and Castell, S. (1994) Physical activity program for older persons: effect on balance, strength, neuromuscular control, and reaction time. *Arch. Phys. Med. Rehabil.* **75**, 648-652.

Lord, S. R., Clark, R. D., and Webster, I. W. (1991) Physiological factors associated with falls in an elderly population. *J. Am. Geriatr. Soc.* **39**, 1194-1200.

Lundberg, A. (1996) On the use of bone and skin markers in kinematics research. *Human Movement Science* **15**, 411-422.

Maki, B., Holliday, P., and Topper, A. (1992) Postural control and prospective risk of falling in the elderly. In: *Posture and Gait: Control Mechanisms*, pp. 291-294. Eds. Woollacott, M.H. and Horak, F.B., University of Oregon Books, Eugene.

Manchester, D., Woollacott, M., Zederbauer-Hylton, N., and Marin, O. (1989) Visual, vestibular and somatosensory contributions to balance control in the older adult. *J. Gerontol.* **44**, M118-M127.

Massion,J. and Woollacott,M.H. (1996) Posture and equilibrium. In: *Clinical Disorders of Balance Posture and Gait*, 1st Ed., pp. 1-18. Eds. Bronstein, A.M., Brandt, T., and Woollacott, M.H., Arnold, Bath.

Mathias, S., Nayak, U. S. L., and Issacs, B. (1986) Balance in elderly patients: the "get up and go" test. *Arch. Phys. Med. Rehabil.* **67**, 387-389.

Mauritz, K. H. (2002) Gait training in hemiplegia. *Eur. J. Neurol.* 9 (Suppl 1:23-9; dicussion 53-61., 23-29.

Maynard, V., Bakheit, A. M., Oldham, J., and Freeman, J. (2003) Intra-rater and inter-rater reliability of gait measurements with CODA mpx30 motion analysis system. *Gait Posture* **17**, 59-67.

McClenaghan, B. A., Williams, H. G., Dickerson, J., Dowda, M., Thombs, L., and Eleazer, P. (1995) Spectral characteristics of ageing postural control. *Gait. Posture* **3**, 123-131.

McMillan, D. E. (1997) Development of vascular complications in diabetes. *Vasc. Med.* **2**, 132-142.

McPoil, T.G. and Hunt, G.C. (1995) An evaluation and treatment paradigm for the future. In: *Physical Therapy of the Foot and Ankle*, 2nd Ed., Eds. McPoil, T.G. and Hunt,G .C., Churchill Livingstone, New York.

Mojica, J. A., Nakamura, R., Kobayashi, T., Handa, T., Morohashi, I., and Watanabe, S. (1988) Effect of ankle-foot orthosis (AFO) on body sway and walking capacity of hemiparetic stroke patients. *Tohoku. J. Exp. Med.* **156**, 395-401.

Montgomery, J. (1987) Assessment and treatment of locomotor deficits in stroke. In: *Stroke Rehabilitation: the Recovery of Motor Control*, pp. 223-259. Edited by Duncan, P.W. and Badke,M.B., Chicago Year Book Publishers, Chicago.

Montgomery, J., and Inaba, M. (1969) Physical therapy techniques in stroke rehabilitation. *Clin. Orthop.* **63**, 63-66.

Morris, J. R. W. (1973) Accelerometry: a technique for the measurement of human body movements. *J. Biomech.* 729.

Motulski,H. (1995) *Intuitive Biostatistics*, Oxford University Press,.New York.

Mueller, K., Cornwall, M., and Mcpoil, T. (1991) Effect of a tone-inhibiting dynamic ankle-foot orthosis on the foot loading pattern of a hemiplegic adult. *Journal of Prosthetics and Orthotics* **4**, 86-92.

Murray, M. P. (1967) Gait as a total pattern of movement. *Am. J. Phys. Med.* **46**, 290-333.

Murray, M. P., Seireg, A. A., and Sepic, S. B. (1975) Normal postural stability and steadiness: quantitative assessment. *J. Bone Joint Surg. Am.* **57**, 510-516.

Nadeau, S., Arsenault, A. B., Gravel, D., and Bourbonnais, D. (1999a) Analysis of the clinical factors determining natural and maximal gait speeds in adults with a stroke. *Am. J. Phys. Med. Rehabil.* **78**, 123-130.

Nadeau, S., Gravel, D., Arsenault, A. B., and Bourbonnais, D. (1999b) Plantarflexor weakness as a limiting factor of gait speed in stroke subjects and the compensating role of hip flexors. *Clin. Biomech.* **14**, 125-135.

Niam, S., Cheung, W., Sullivan, P. E., Kent, S., and Gu, X. (1999) Balance and physical impairments after stroke. *Arch. Phys. Med. Rehabil.* **80**, 1227-1233.

Niemi, M. L., Laaksonen, R., Kotila, M., and Waltimo, O. (1988) Quality of life 4 years after stroke. *Stroke* **19**, 1101-1107.

Nougier, V., Bard, C., Fleury, M., and Teasdale, N. (1997) Contribution of central and peripheral vision to the regulation of stance. *Gait. Posture* **5**, 34-40.

Nouri, F. M., and Lincoln, N. B. (1987) An extended activities of daily living scale for stroke patients. *Clinical Rehabilitation* **1**, 301-305.

Olney, S. J., Elkin, N., and Lowe, P. (1979) An ambulation profile for clinical gait evaluation. *Physiother. Can.* **31**, 85-90.

Olney, S. J., Griffin, M. P., and McBride, I. D. (1994) Temporal, kinematic, and kinetic variables related to gait speed in subjects with hemiplegia: a regression approach. *Phys. Ther.* **74**, 872-885.

Olney, S. J., Griffin, M. P., Monga, T. N., and McBride, I. D. (1991) Work and power in gait of stroke patients. *Arch. Phys. Med. Rehabil.* **72**, 309-314.

Olney, S. J., and Richards, C. (1996) Hemiparetic gait following stroke. Part 1:Characteristics. *Gait Posture* **4**, 136-148.

Overby, A. S., Lubin, L., Goudelach, C., and Scarborough, N. (1991) Single case study on tone inhibiting AFO in adult hemiplegic subject. *Phys. Ther.* **71**, R226.

Öberg, T, Karsznia, A., and berg, K. (1993) Basic gait parameters: reference data for normal subjects, 10-79 years of age. *J. Rehabil. Res. Dev.* **30**, 210-223.

Partridge, C. J., Morris, L. W., and Edwards, M. S. (1993) Recovery from physical disability after stroke: profiles for different levels of starting severity. *Clin. Rehabil.* **7**, 210-217.

Patla, A.E. (1996) Neurobiomechanical bases for the control of human locomotion. In: *Clinical Disorders of Balance Posture and Gait*, 1st Ed., pp. 19-40. Eds. Bronstein,A.M., Brandt,T., and Woollacott, M.H., Arnold, Bath.

Patla, A. E., Frank, J. S., and Winter, D. A. (1990) Assessment of balance control in the elderly: major issues. *Physiother. Can.* **42**, 89-97.

Perry, J. (1969) Lower-extremity bracing in hemiplegia. *Clin. Orthop.* **63**, 32-38.

Perry, J., Garrett, M., Gronley, J. K., and Mulroy, S. J. (1995) Classification of walking handicap in the stroke population. *Stroke* **26**, 982-989.

Pinzur, M. S., Sherman, R., DiMonte-Levine, P., and Trimble, J. (1987) Gait changes in adult onset hemiplegia. *Am. J. Phys. Med.* **66**, 228-237.

Pollack, A., Langhorne, P., Baer, G., and Pomeroy, V. (2002) Physiotherapy treatment approaches for the recovery of postural control and lower limb function following stroke. *The Cochrane Database of Systematic Reviews* **1**, 1-15.

Pomeroy, V., and Tallis, R. C. (2002) Restoring movement and functional ability after stroke. *Physiotherapy* **88**, 3-17.

Portfors-Yeomans, C. V., and Riach, C. L. (1995) Frequency characteristics of postural control of children with and without visual impairment. *Dev. Med. Child Neurol.* **37**, 456-463.

Potter, J. M., Evans, A. L., and Duncan, G. (1995) Gait speed and activities of daily living function in geriatric patients. *Arch. Phys. Med. Rehabil.* **76**, 997-999.

Prince, F., Corriveay, H., Hébert, R., and Winter, D. A. (1997) Gait in the elderly. *Gait. Posture* **5**, 128-135.

Pushpangadan, M., Wright, J., and Young, J. (1999) Evidence-based guidelines for early stroke management. *Hosp. Med.* **60**, 105-114.

Quoniam, C., Hay, L., Roll, J. P., and Harlay, F. (1995) Age effects on reflex and postural responses to propriomuscular inputs generated by tendon vibration. *J. Gerontol. A Biol. Scl Med. Sci* **50**, B155-B165.

Radin, E. L., Yang, K. H., Riegger, C., Kish, V. L., and O'Connor, J. J. (1991) Relationship between lower limb dynamics and knee joint pain. *J. Orthop. Res.* **9**, 398-405.

Reding, M. J., and McDowell, F. (1987) Stroke rehabilitation. *Neurol. Clin.* **5**, 601-630.

Richards, C.L., Malouin,F., Dumas,F., and Tardif,D. (1995) Gait velecity as an outcome measure of locomotor recovery after stroke. In: *Gait Analysis: Theory and Application*, 1st Ed., pp. 355-364. Eds. Craik, R.L. and Oatis, C.A., Mosby, Missouri.

Richards, C. L., Malouin, F., Wood-Dauphinee, S., Williams, J. I. , Bouchard, J. P., and Brunet, D. (1993) Task-specific physical therapy for optimization of gait recovery in acute stroke patients. *Arch. Phys. Med. Rehabil.* **74**, 612-620.

Ringsberg, K., Gerdhem, P., Johansson, J., and Obrant, K. J. (1999) Is there a relationship between balance, gait performance and muscular strength in 75-year-old women? *Age Ageing* **28**, 289-293.

Roberts, E. M., Cheung, T. K., Hafez, A., and Hong, D. (1997) Swing limb biomechanics of 60-65 year old male runners. *Gait. Posture* **5**, 42-53.

Romkes, J., and Brunner, R. (2002) Comparison of a dynamic and a hinged ankle-foot orthosis by gait analysis in patients with hemiplegic cerebral palsy. *Gait. Posture.* **15**, 18-24.

Rosamond, W. D., Folsom, A. R., Chambless, L. E., Wang, C. H., McGovern, P. G., Howard, G., Copper, L. S., and Shahar, E. (1999) Stroke incidence and survival among middle-aged adults: 9-year follow-up of the Atherosclerosis Risk in Communities (ARIC) cohort. *Stroke* **30**, 736-743.

Roth, E. J., Merbitz, C., Mroczek, K., Dugan, S. A., and Suh, W. W. (1997) Hemiplegic gait. Relationships between walking speed and other temporal parameters. *Am. J. Phys. Med. Rehabil.* **76**, 128-133.

Sackley, C. M. (1991) Falls, sway, and symmetry of weight-bearing after stroke. *Int. Disabil. Stud.* **13**, 1-4.

Sackley, C. M., and Lincoln, N. B. (1996) Physiotherapy treatment for stroke patients: survey of current practice. *Physiother. Theo. Prac.* **12**, 87-96.

Saladin, L.K. (1996) Cerebrovascular disease: stroke. In: *Pathophysiology of the Motor Systems: Principles and Clinical Presentations*, pp. 486-512. Edited by Fredericks,C.P. and Saladin,L.K., F.A. Davis Company, Philadelphia.

Salford Royal Hospital NHS Trust.Executive Board Paper. (1995) Stroke Service Audit Report (June-September).

Salo, A. (1999) An Assessment of Video Motion Analysis - Variability, Reliability, Camera Orientation and Extrapolation. 89-108. The University of Exeter.

Salo, A., Grimshaw, P. N., Mononen, H. V., and Viitasalo, J. T. (1996) Variation in motion analysis of sprint hurdles: Part 1 - co-ordinate deviation in 3-dimensional reconstruction. *J. M. C. S (ed.) Proceedings of the XIV ISBS Symposium*, 262-265.

Salo, A., Grimshaw, P. N., Mononen, H. V., and Viitasalo, J. T. (1996) Variation in motion analysis of sprint hurdles: Part II - the influence of co-ordinate variation on performance variables. *J. M. C. S (ed.) Proceedings of the XIV ISBS Symposium*, 266-269.

Salo, A., Grimshaw, P. N., and Viitasalo, J. T. (1997) Reliability of variables in the kinematic analysis of sprint hurdles. *Med. Sci. Sports. Exerc.* **29**, 383-389.

Sandercock, P., and Willems, H. (1992) Medical treatment of acute ischaemic stroke. *Lancet* **339**, 537-539.

Sarno, J. E., and Lehneis, H. R. (1971) Prescription considerations for plastic below-knee orthoses. *Arch. Phys. Med. Rehabil.* **52**, 503-510.

Saunders, D. H., Greig, C. A., Young, A., and Mead, G. E. (2002) Physical fitness training for stroke patients. *The Cochrane Database of Systematic Reviews* **1**, 1-16.

Sherrington, C., and Lord, S. R. (1997) Home exercise to improve strength and walking velocity after hip fracture: a randomized controlled trial. *Arch. Phys. Med. Rehabil.* **78**, 208-212.

Shiavi, R., Bugle, H. J., and Limbird, T. (1987a) Electromyographic gait assessment, Part 1: Adult EMG profiles and walking speed. *J. Rehabil. Res. Dev.* **24**, 13-23.

Shiavi, R., Bugle, H. J., and Limbird, T. (1987b) Electromyographic gait assessment, Part 2: Preliminary assessment of hemiparetic synergy patterns. *J. Rehabil. Res. Dev.* **24**, 24-30.

Shumway-Cook, A., Anson, D., and Haller, S. (1988) Postural sway biofeedback: its effect on reestablishing stance stability in hemiplegic patients. *Arch. Phys. Med. Rehabil.* **69**, 395-400.

Shumway-Cook, A. and Woollacott, M.H. (1995) *Motor Control. Theory and Practical Applications*, pp. 295-314, Williams and Wilkins, Philadelphia.

Sim, J., and Reid, N. (1999) Statistical inference by confidence intervals: issues of interpretation and utilization. *Phys. Ther.* **79**, 186-195.

Smith, D. L., Akhtar, A. J., and Garraway, W. M. (1985) Motor function after stroke. *Age. Aging* **14**, 46-48.

Sparkes, V. (2000) Physiotherapy for stroke rehabiliation. *Physiotherapy* **86**, 348-356.

Stegmayr, B., Vinogradova, T., Malyutina, S., Peltonen, M., Nikitin, Y., and Asplund, K. (2000) Widening gap of stroke between east and west. Eight-year trends in occurrence and risk factors in Russia and Sweden. *Stroke* **31**, 2-8.

Stokes, M. (1986) Reliability and repeatability of methods for measuring muscle in physiotherapy. *Physiother. Prac.* **1**, 71-76.

Stolze, H., Kuhtz-Buschbeck, J. P., Mondwurf, C., Johnk, K., and Friege, L. (1998) Retest reliability of spatiotemporal gait parameters in children and adults. *Gait. Posture* **7**, 125-130.

Stroke Unit Trialists' Collaboration (2001) Organised inpatient (stroke unit) care for stroke. In: *The Cochane Library Issue 1*, Update Software, Oxford.

Sulch, D., Melbourn, A., Perez, I., and Kalra, L. (2002) Integrated care pathways and quality of life on a stroke rehabilitation unit. *Stroke* **33**, 1600-1604.

Sutherland, D. (1997) The development of mature gait. *Gait. Posture* **6**, 163-170.

Teasdale, N., Stelmach, G. E., and Breunig, A. (1991) Postural sway characteristics of the elderly under normal and altered visual and support surface conditions. *J. Gerontol.* **46**, B238-B244.

Teasell, R., McRae, M., Foley, N., and Bhardwaj, A. (2002) The incidence and consequences of falls in stroke patients during inpatient rehabilitation: factors associated with high risk. *Arch. Phys. Med. Rehabil.* **83**, 329-333.

Teasell, R. W., McRae, M. P., Foley, N., and Bhardwaj, A. (2001) Physical and functional correlations of ankle-foot orthosis use in the rehabilitation of stroke patients. *Arch. Phys. Med. Rehabil.* **82**, 1047-1049.

Thomas, S. S., Buckon, C. E., Jakobson-Huston, S., Sussman, M. D. , and Aiona, M. D. (2002) Stair locomotion in chidren with spastic hemoplegia: the impact of three different ankle foot othosis (AFOs) configurations. *Gait. Posture* **16**, 180-187.

Thorvaldsen, P., Asplund, K., Kuulasmaa, K., Rajakangas, A. M., and Schroll, M. (1995) Stroke incidence, case fatality, and mortality in the WHO MONICA project. World Health Organization Monitoring Trends and Determinants in Cardiovascular Disease. *Stroke* **26**, 361-367.

Titianova, E. B., and Tarkka, I. M. (1995) Asymmetry in walking performance and postural sway in patients with chronic unilateral cerebral infarction. *J. Rehabil. Res. Dev.* **32**, 236-244.

Toller, J., Carleton, G., Fencott, P, and Watkins, B. (1989) The use of hinged ankle-foot orthoses (AFO) to control excessive dorsiflexion or plantarflexion. *Physiotherapy Canada* **41** (Suppl.3), 9.

Toupet, M., Gage,P., and Heuschen,S. (1992) Vestibular patients and aging subjects loose use of visual input and expend more energy in static postural control. In: *Falls, Balance and Gait Disorders in the Elderly*, Eds. Vellas, B., Toupet, M., Rubenstein, L.Z., Albarded, J., and Christen, Y., Elsevier, Paris.

Traynelis, S. F., and Lipton, S. A. (2001) Is tissue plasminogen activator a threat to neurons? *Nat. Med.* **7**, 17-18.

Turnbull, G. I., Charteris, J., and Wall, J. C. (1995) A comparison of the range of walking speeds between normal and hemiplegic subjects. *Scand. J. Rehabil. Med.* **27**, 175-182.

Turton, A., Wroe, S., Trepte, N., Fraser, C., and Lemon, R. N. (1996) Contralateral and ipsilateral EMG responses to transcranial magnetic stimulation during recovery of arm and hand function after stroke. *Electroencephalogr. Clin. Neurophysiol.* **101**, 316-328.

Tyson, S. F., and Thornton, H. A. (2001) The effect of a hinged ankle foot orthosis on hemiplegic gait: objective measures and users' opinions. *Clin. Rehabil.* **15**, 53-58.

Tyson, S. F., Thornton, H. A., and Downes, A. (1998) The effect of a hinged ankle-foot orthosis on hemiplegic gait: Four single case studies. *Physiother. Theo. Prac.* **14**, 75-85.

Uutela, A. E. and Bowker P. (1998) Effect of Dynamic Ankle-Foot Orthoses on stroke patients' gait. *IXth World Congress of The International Society for Prosthetics and Orthotics.* The Netherlands, June 28 - July 3. Abstract and oral communication.

Uutela, A. E. and Bowker, P. (2003) The effect of dynamic ankle-foot orthose on the gait of stroke patients. RR-PL-1767. *World Conference of Physical Therapy, Barcelona*, 7 – 12 June. Abstract and oral communication.

van Vliet, P. (1988) Kinematic analysis of videotape to measure walking following stroke: a case study. *Australian Journal of Physiotherapy* **34**, 48-51.

von Koch, L., Wottrich, A. W., and Holmqvist, L. W. (1998) Rehabilitation in the home versus the hospital: the importance of context. *Disabil. Rehabil.* **20**, 367-372.

von Schroeder, H. P., Coutts, R. D., Lyden, P. D., Billings, E. Jr, and Nickel, V. L. (1995) Gait parameters following stroke: a practical assessment. *J. Rehabil. Res. Dev.* **32**, 25-31.

Wade, D.T. (1992) *Measurement in Neurological Rehabilitation*, pp. 75-76, Oxford Medical Publications, New York.

Wade, D. T., and Hewer, R. L. (1987) Functional abilities after stroke: measurement, natural history and prognosis. *J. Neurol. Neurosurg. Psychiatry* **50**, 177-182.

Wade, D. T., Wood, V. A., Heller, A., Maggs, J., and Langton, Hewer R. (1987) Walking after stroke. Measurement and recovery over the first 3 months. *Scand. J. Rehabil. Med.* **19**, 25-30.

Wade, D. T., Wood, V. A., and Langton-Hewer, R. (1985) Recovery after stroke-the first 3 months. *J. Neurol. Neurosurg. Psychiatry* **48**, 7-13.

Wade, L. D., Canning, C. G., Fowler, V., Felmingham, K. L., and Baguley, I. J. (1997) Changes in postural sway and performance of functional tasks during rehabilitation after traumatic brain injury. *Arch. Phys. Med. Rehabil.* **78**, 1107-1111.

Wadell, I., Kusoffsky, A., and Nilsson, B. Y. (1987) A follow-up study of stroke patients 5-6 years after their brain infarct. *Int. J. Rehabil. Res.* **10**, 103-110.

Wagenaar, R. C., and Beek, W. J. (1992) Hemiplegic gait: a kinematic analysis using walking speed as a basis. *J. Biomech.* **25**, 1007-1015.

Walker, C., Brouwer, B. J., and Culham, E. G. (2000) Use of visual feedback in retraining balance following acute stroke. *Phys. Ther.* **80**, 886-895.

Wall, J. C., and Crosbie, J. (1995) Accuracy and reliability of temporal gait measurement. *Gait. Posture* **4**, 293-296.

Walsh, W.P. (1995) Foot fall measurement technology. In: *Gait Analysis: Theory and Application*, 1st Ed., pp. 125-142. Eds. Craik, R.L. and Oatis,C.A., Mosby, Missouri.

Warlow, C., Dennis,M.S., van Gijn,J., Hankey,G.J., Sandercock,P., Bamford,J., and Wardlaw,J.M. (2001) *Stroke: A Practical Guide to Management*, Blackwell Science,London.

Whittle, M.W. (1998) Normal gait. In: *Gait Analysis: An Introduction*, 2nd Ed., pp. 53-107. Edited by Whittle, M.W., Butterworth-Heinmann, Oxford.

WHO (1980) International classification of impairments, disabilities and handicaps. Geneva.

WHO. (2001) *International Classification of Functioning, Disability and Health: ICF.*

Williams, H. G., McClenaghan, B. A., and Dickerson, J. (1997) Spectral characteristics of postural control in elderly individuals. *Arch. Phys. Med. Rehabil.* **78**, 737-744.

Wing, A. M., Goodrich, S., Virji-Babul, N., Jenner, J. R., and Clapp, S. (1993) Balance evaluation in hemiparetic stroke patients using lateral forces applied to the hip. *Arch. Phys. Med. Rehabil.* **74**, 292-299.

Winstein, C. J., Gardner, E. R., McNeal, D. R., Barto, P. S., and Nicholson, D. E. (1989) Standing balance training: effect on balance and locomotion in hemiparetic adults. *Arch. Phys. Med. Rehabil.* **70**, 755-762.

Winter, D. A. (1974) Kinematics of normal locomotion: a statistical study based on T.V data. *J. Biomech.* **7**, 479.

Winter, D. A. (1984) Kinematic and kinetic patterns in human gait: variability and compensating effects. *Human Movement Science* **3**, 51-76.

Winter, D.A. (1990) Kinematics. In: *Biomechanics and Motor Control of Human Movement*, 2nd Ed., pp. 45-50., John Wiley & Sons, Inc., Toronto.

Winter, D.A. (1991a) Gait analysis: considerations and terminology. In: *The Biomechanics and Motor Control of Human Gait: Normal, Elderly and Pathological*, 2nd Ed., pp. 1-10., Waterloo Press, Ontario.

Winter, D.A. (1991b) The Biomechanics and motor control of human gait: normal elderly and pathological. In: 2nd Ed., pp. 11-16., University of Waterloo Press, Waterloo.

Winter, D. A. (1995) Human balance and postural control during standing and walking. *Gait. Posture* **3**, 193-214.

Winter, D. A., Prince, F., Frank, J. S., Powell, C., and Zabjek, K. F. (1996) Unified theory regarding A/P and M/L balance in quiet stance. *J. Neurophysiol.* **75**, 2334-2343.

Witte, U. S., and Carlsson, J. Y. (1997) Self-selected walking speed in patients with hemiparesis after stroke. *Scand. J. Rehabil. Med.* **29**, 161-165.

Wolf, P.A., Cobb, J.L., and D`Agostino,R.B. (1992) Epidemiology of stroke. In: *Stroke: Pathophysiology, Diagnosis and Management*, 2nd Ed., Edited by Barnett, H.J.M., Churchill Livingstone, New York.

Wolley, S. M., Horn, L. J., and Commager, J. A. (1996) The effect of Orthotic intervention in patients with hemiparesis. *Gait. Posture* **4** (Abstract), 185.

Woltring, H. J. (1984) An optional smoothing and derivative estimation fro noisy displacement data in biomechanics . *Human Movement Science* **3**, 229.

Wong, A. M., Tang, F. T., Wu, S. H., and Chen, C. M. (1992) Clinical trial of a low-temperature plastic anterior ankle foot orthosis. *Am. J. Phys. Med. Rehabil.* **71**, 41-43.

Wooley, S. A. (2001) Characteristics of gait in hemiplegia. *Top. Stroke Rehabil.* **7**, 1-18.

Woollacott, M., and Shumway-Cook, A. (2002) Attention and the control of posture and gait: a review of an emerging area of research. *Gait. Posture* **16**, 1-14.

Woollacott, M. H. (1993) Age-related changes in posture and movement. *J. Gerontol.* **48**, 56-60.

Woollacott, M. H., Shumway-Cook, A., and Nashner, L. M. (1986) Aging and posture control: changes in sensory organization and muscular coordination. *Int. J. Aging Hum. Dev.* **23**, 97-114.

Wu, G. (1995a) A review of body segmental displacement, velocity, and acceleration in human gait. In: *Gait Analysis: Theory and Application*, 1st Ed., pp. 205-222. Eds. Craik, R.L. and Oatis, C.A., Mosby, Missouri.

Wu, G. (1995b) Kinematics theory. In: *Gait Analysis: Theory and Application*, 1st Ed., pp. 159-182. Eds. Craik, R.L. and Oatis, C.A., Mosby, Missouri.

Wu, G., and Cavanagh, P. R. (1995) ISB recommendations for standardization in the reporting of kinematic data. *J. Biomech.* **28**, 1257-1261.

Wulf, G., McNevin, N., and van Vliet, P. (2003) Motor learning. Focus symposium. *World Conference of Physical Therapy, Barcelona* , 100.

Yamada, K. A. (1998) Modulating excitatory synaptic neurotransmission: potential treatment for neurological disease? *Neurobiol. Dis.* **5**, 67-80.

7 APPENDICES		**310**
APPENDIX I	Pilot study	311
APPENDIX II	DAFO fabrication	325
APPENDIX III	Information sheet, evaluation forms, muscle tests and results	335
APPENDIX IV	Balance equations	350

APPENDIX I

Pilot study

The pilot study consisted of preliminary measurements of stroke patients' balance and gait characteristics, together with functional assessments of neurological disability. The principle aim of the work was to assess methods for subject recruitment, and the design, manufacture and provision of orthoses. In addition, these investigations aimed to provide information on the clinical practicalities and likely effectiveness of the planned main phase studies. It was predicted that the work would: 1) clarify the procedures and objectivity of the subject inclusion and exclusion criteria, 2) indicate the timescales required for fabrication of orthoses, 3) enable the author to develop proficiency in performing the experimental procedures and 4) provide preliminary data on how DAFOs affect stroke patients balance and gait. The studies were undertaken over a nine months period at the onset of this research project. Here, the outcome of the studies with emphasis on development of the methods for the main phase is described and preliminary data acquired are presented; details of orthotic design, manufacture and provision are covered in detail in Appendix II.

Subjects

Stroke patients admitted for rehabilitation to the Stroke Unit at the Salford Royal Hospitals NHS Trust (Ladywell and Hope Hospitals) from November 1995 to February 1996 were considered for study. Patient recruitment involved detailed clinical assessment and criteria evaluation before informed and written consent was sought from potential subjects (section 2.1.1). In some cases, patients were excluded where assessment of case notes by the Stroke Unit's consultant medical staff concluded that a subject's particularly poor physical condition precluded them from participating in gait laboratory tests of extended duration. Three stroke patients met the initial entry criteria (section 2.1.2) and agreed to take part in the pilot study by signing the consent form.

Arrangements were made for the construction of a DAFO appropriate for each subject's gait impairment (Appendix II). The prescription for orthoses was based on observational evaluation of subjects' gait by the orthotist and the author while the subjects were hospital inpatients. During this stage, one of the subjects withdrew for personal reasons; the pilot trials therefore proceeded with two stroke patients. Both subjects had suffered a right side cerebral infarction and left side hemiparesis; demographic details are summarised in Table A1.1.

Table A1.1 Demographic details of subjects

Subject code	Sex	Age	Side of paresis	Time since stroke
P1	F	67 years	Left	3 months
P2	M	56 years	Left	3 months

Subject *P1* was able to walk indoors with supervision, however a helper was required when walking outside. Her trunk was rotated to the left with a forward lean; her left arm was flat down with no activity. During stance phase the trunk flexed over to the left side to maintain balance and the left hip was flexed. Stance phase was shorter on the affected side. The left heel strike was low and occasionally initial contact was made with the foot flat. In stance phase the left ankle was in supination/inversion, whereas the forefoot was in pronation with the medial arch lowered. On the unaffected side, the forefoot was also in pronation and the medial arch was low during the stance phase. During swing phase, the hip and knee flexed more on the left side and, occasionally, the toes touched the floor, giving the subject an 'unstable feeling'. The subject was prescribed a DAFO designed to support the forefoot pronation position and stabilize the subtalar joint inversion. It was clear that the subject's gait was affected by a lack of

confidence, which resulted in further instability, both when walking in the gait laboratory and during day-to-day living.

Subject *P2* could walk inside with a stick and supervision for about 10 meters; a wheelchair was used for longer distances outside. His walking was unstable because of inadequate muscle activity due to hypertonic muscle extension on the affected side, preventing smooth leg movement. The gait pattern was asymmetrical, and the stance phase was greatly extended on the unaffected side. The step with the affected leg was long with the trunk leant backwards and rotated. The forefoot made the initial contact and the stance phase was very short. Weight was borne primarily on the lateral border of the affected foot with the toes flexed. The subject had difficulty to move his weight to the left leg. The affected knee was hyperextended throughout the duration of the stance phase. During swing phase, the affected leg clearance was inadequate due to limited motions of hip flexion, knee flexion, and ankle dorsiflexion. The trunk was rotated to the left side and the pelvis was retracted during swing phase. The affected ankle was in supination/inversion during swing phase, together with forefoot inversion and flexion of the toes. The subject was prescribed a DAFO designed to support the subtalar joint and the forefoot in a neutral position.

As indicated earlier, the orthoses were constructed for the subjects after subjective gait evaluation by the orthotist and the author. However, because of the patients' early state of recovery and active rehabilitation time, gait problems can vary considerably. Subjective evaluation proved to be difficult, as the decision for the specific design of orthosis to be used had to be made quickly, i.e. within the six weeks period the subject was an in-patient at the stroke unit. Consequently, modification of the evaluation strategy was required. The muscle strength test has been shown to be a useful evaluation method during stroke patients' recovery (Jorgensen *et al.*, 1995) and was used here. It was predicted that the test when used for the lower limbs would highlight gait problems and aid prescription of the model of DAFO. Medical Research Council

(MRC) grades are commonly used as an ordinal measure of power (Demeurisse *et al.*, 1980). In this system, the muscle power is graded as follows: 0 = no movement; 1 = palpable contraction but no visible movement; 2 = movement but only with gravity eliminated; 3 = movement against gravity; 4 = movement against resistance but weaker than other side; 5 = normal power. The muscles of the lower limbs were tested manually with ankle flexion/extension movements, and knee flexion/extension and hip flexion/ extension movements, in a sitting or lying position, depending on muscle activity. The values obtained from these tests (not shown) were used as an indication of muscle activity when prescribing the DAFO.

Orthosis

For these studies two subjects were supplied with and wore a DAFO for one month. Fabrication required 2-3 weeks and a further 10 days for purchasing new shoes and fittings the new orthosis. This time-scale was later found to be impractical, because of the duration of stroke patients' treatment in the stroke unit. During the main trial it was endeavoured to limit the fabrication and fitting time to three weeks. This was possible by reducing the fabrication time to one week and the fitting time to two weeks. The patients were encouraged to purchase shoes as soon as convenient after provision of the orthosis. Although the patients and their relatives were initially enthusiastic about buying shoes for the orthoses, both subjects experienced difficulty in purchasing suitable leather shoes and instead opted for 'training shoes'. It was envisaged that in the main phase studies some patients' relatives would be unwilling to buy new shoes. It was also reasonable to assume that several of the patients in the main study would have no living relatives. For these reasons, during the main study phase, arrangements were made for the author to accompany and advise patients during purchase of the shoes and, where necessary, the cost was met using monies provided from the research budget. During the initial accustomisation period both subjects experienced discomfort and pain over the dorsum of the foot, which was attributable to friction between the DAFO and the skin

surface. The DAFOs were therefore padded inside with plastatzote for the remainder of the trial and no further discomfort was reported. During the main study phase, all of the DAFOs were modified accordingly.

Testing procedures

Because of the limited time schedule and availability of suitable subjects for the pilot study, it was apparent that there would be difficulties amassing a sufficient numbers of subjects matching the inclusion criteria. For this reason a single case design was performed. The subjects' balance, gait characteristics and functional abilities were tested over a six weeks long experimental trial consisting of four data collections at two-weekly intervals (Table A1.2). During the balance and gait tests, the subjects were tested under two experimental conditions during each data collection: using only shoes and then using a DAFO fitted inside a casual shoe. Each subject served as his/her own control. Each testing session concluded with a functional assessment. During the last week of testing, one subject (*P1*) had an accident (unrelated to the study) breaking her upper arm. This subject was therefore tested on three out of the four possible occasions.

Table A1.2 Testing procedure design: the first test represented a baseline, which was followed by three further tests over six weeks. Each test consisted of balance-, gait- and functional-assessments.

	Week 0 (Baseline)	**Week 2**	**Week 4**	**Week 6**
Subjects tested with shoes-alone and with DAFOs	**1)** Balance test **2)** 10 m gait test **3)** Functional test	Measurement repeated	Measurement repeated	Measurement repeated

The first test collection defined a baseline coinciding with when the subject started to use orthoses. The next three tests indicated the time frame for orthosis familiarisation and whether there were any obvious changes with orthosis use. In addition, using the single-case design, it was possible to obtain reasonable amounts of preliminary data for determination of any beneficial effects due to the orthosis, particularly in relation to influences on standing balance and gait parameters (Wilson 1995).

Methods - Balance

The body sway during standing was measured using a piezoelectric force platform (Kistler Instrument Ltd.) connected to a PC running Bioware software, as the subjects performed two 30-second tests with eyes-open and with eyes-closed. Positional changes of the CoP over time were monitored. These methods initially used to study the stroke subjects' balance were found to be mostly adequate, and no modifications were required for their use in the main studies. However, it was found that some of the variables analysed (e.g. SD of the CoP) provided limited information on balance. Consequently, the design of the main studies was expanded to include assessment of additional variables; a full description of the methods was given in section 2.4.

Methods - Gait

Gait evaluation tests were carried out after the balance measurements. Subjects' gait was recorded using 'step-analyser' apparatus and two video cameras (Panasonic M2 2, VHS 625, speed 25 field/s) viewed in saggittal and frontal planes. After setting up the recording equipment (described later) the subject was asked to walk a 10 m distance in a straight line, using whatever aid required and at self-selected pace. Four separate measurements were made with the subject resting after each measurement (usually by sitting on a chair).

Each subject's gait was recorded simultaneously with the 'step-analyser' and video based movement analysis systems. The 'step-analyser' foot-switch system monitors

pressure from four plantar locations, and provides data describing the plantar aspect (foot-fall parameters) of the subject's foot during walking. One FSR was taped under the subject's heel and one under the third metatarsal, at the interface between the foot and the shoe and between the shoe and DAFO. The four FSRs were connected via thin cables to the data-logger, which collected the output from the sensors at a rate of 200-500 samples per second, for a maximum of 32 seconds. The data-logger was attached to the receiver box, which stored the data during the gait test prior to downloading to a PC.

Lower limb movements during gait were analysed in two-dimensions. Gait was recorded in the sagittal plane with a video camera (Panasonic MS2, speed 25 frames/sec) in the middle of the 10-metre walkway, where 2.5 m before the recording area was designated as the point where a natural speed of gait was achieved and 2.5 m after this defined a slowdown' area. Successful data collection was repeated four times: twice with shoes only and twice with the orthosis. For the study of gait kinematics, skin markers were placed at the head of the fifth metatarsal, the heel, the lateral malleolus, the lateral epicondyle and the greater trochanter of the hip. This marker set identifies the locations of the lower limbs 5-segment performance model. The video data were filtered (Quintic spline) and differentiated (Ariel Performance Analysis System). In order to describe subjects' movement, gait velocity, the forefoot and the heel markers linear displacement, and the ankle and knee joints angular displacements were monitored. Gait velocity was selected as a description of subjects' overall gait ability.

Results - Balance

The variability (SD) of the CoP as a function of time (30 s), which indicates the location where the resultant ground reaction force applies to the feet, was used as a measure of stability of subjects while quite standing. The SD of the mean value from the repeated trials was used as an index of the amount of sway during quite standing (Era and

Heikkinen, 1985). Lower sway index values are considered to reflect steady standing position (Tang and Woollacott, 1996).

Sway Index - subject *P1*

During the baseline test, the sway index for subject *P1* in the a-p direction with eyes-open was 5.58 (0.79) with shoes, and 5.84 (0.53) with the DAFO, mean and (SD). For the second test, the sway indices recorded were slightly increased compared to baseline, at 8.16 (0.68) with shoes and 14.18 (1.35) with the DAFO. In the third test, the sway indices returned to near baseline levels, at 4.40 (0.95) and 5.72 (0.11). In the a-p direction with eyes-closed, the sway indices were clearly higher than for the eyes-open condition. It was also found that the values recorded throughout the three tests were slightly lower with shoes than with the DAFO. Thus, for the baseline test, the sway index of subject *P1* with shoes was 8.62 (1.99) and 10.84 (2.88) with the DAFO. For the second and third tests, the sway indices were 9.34 (2.90) and 10.94 (1.25), and 7.65 (0.95) and 10.68 (3.73), with shoes and the DAFO, respectively.

In the lateral direction, with eyes-open, the sway indices for subject *P1* recorded during the baseline test were 8.50 (2.44) with shoes and 7.52 (0.02) with the DAFO. In the second and third tests the corresponding values recorded were 11.11 (1.13) and 14.03 (0.95), and 4.99 (0.93) and 7.68 (0.69). The lateral sway indices with eyes-closed for the baseline test were 9.92 (0.09) using shoes and 12.93 (1.95) using DAFOs. The measurements for the second test were 10.75 (4.13) with shoes and 10.74 (2.33) with DAFOs. In the third test, values of 10.75 (1.50) and 14.19 (0.15) were recorded. These data suggested that, for this subject, there were no clear effects on standing balance characteristics when using a DAFO compared to using shoes alone over the testing trial period.

Sway index - subject *P2*

In contrast to subject *P1*, subject *P2* took part in the full 6 weeks testing protocol comprising 4 balance tests. For the baseline test, the sway indices in the a-p direction with eyes-open were 5.71 (0.62) with shoes and 6.78 (0.24) with the DAFO. The corresponding values recorded during the three remaining tests were very similar to baseline, at 5.35 (0.06) and 6.93 (0.89) [test 2], 6.09 (1.22) and 6.08 (2.19) [test 3] and 6.76 (1.34) and 6.77 (1.16) [test 4]. In the a-p direction with eyes-closed, the sway indices were higher than for the eyes-open condition. Thus, during the baseline test, the sway index for subject *P2* was 7.77 (0.86) with shoes and 9.73 (0.86) with the DAFO. For the second and third tests, the sway indices recorded with shoes and the DAFO were, respectively, 10.42 (0.0), 9.06 (1.45), and 6.09 (1.22), 6.08 (2.19). Similar values were obtained during the third test, at 6.76 (1.35) and 6.77 (1.16).

The sway indices for subject *P2* recorded in the lateral direction for the eyes-open condition during the baseline test were 8.89 (2.08) with shoes and 9.57 (1.17) with the DAFO. In the second and third tests, the corresponding values recorded were 6.30 (0.94), 7.16 (1.99) and 7.03 (0.52), 6.24 (1.77). In the fourth test, the sway indices were marginally higher than those obtained from the third test, at 8.92 (1.79) and 8.07 (0.55). The lateral sway indices with eyes-closed for the baseline test were 10.27 (0.02) using shoes and 11.88 (0.72) using the DAFO. The second test values recorded were 13.44 (0.41) and 14.02 (0.65). Measurements collected during the third test yielded values of 10.6 (0.11) and 12.47 (1.92). The fourth test values were considerably lower than for the previous test recordings, at 7.26 (0.01) and 11.34 (3.53).

As was found for subject *P1*, the data indicate that the standing balance characteristics for subject *P2* were not clearly affected when using the DAFO compared to shoes. However, with this subject, noticeable lower values were recorded for the sway index with DAFOs than with shoes alone, in the third and forth tests. This was seen particularly for the a-p sway in the eyes-closed condition and for the lateral sway with

eyes-open. The lower balance values obtained for some of the tests suggested better balance control with DAFO intervention.

Results - Gait

The gait velocities recorded for both subjects during the tests ranged from 0.04 to 0.50 m/sec. Subject *P1* had an intermediate gait velocity (mean 0.43 m/sec), which approximated 35% of the reported age-specific free-walking speed (Judge *et.al.*, 1996). Subject *P2* displayed a slower gait velocity (mean 0.08 m/sec), which was 10% of the normal free-walking speed. There were no differences observed between gait velocities within individual tests. However, when data for each condition were collated (with the DAFO or with shoes alone), the mean gait velocity appeared slightly improved (increased) with shoes compared to the DAFO, for both patients.

In these studies, the subjects' kinematic gait analysis was described using a linear displacement parameter in the saggital plane. The linear displacement of the foot was calculated from the heel and toe markers during one gait cycle, to provide information about the stroke subjects' gait pattern using the DAFO. Data from both the affected and unaffected leg were collected and analysed.

Although subject *P1* had an intermediate gait velocity, her kinematic gait pattern was highly compatible with published databases for healthy subjects (Winter, 1974). No clear differences in lower limb ankle and knee joint linear and angular displacement (on the unaffected and affected sides) were observed when wearing the DAFO compared to shoes alone.

For subject *P2*, who was a very slow walker, the push-off phase commenced earlier on the unaffected side when using the DAFO compared to using shoes; this was seen in tests 1, 2, and 4. This increased swing phase on the unaffected side could suggests better stability on the affected side, and a more symmetrical gait while using DAFO when walking problems are severe.

Subject *P2* possessed an extended stance phase on the affected side (70-90% of his gait cycle) whilst the swing phase was 50-70% shorter than expected according to healthy subjects' gait data (Murray, 1967; Craik and Dutterer, 1995). This pattern was maintained throughout all four testing trials and under both experimental conditions. Using shoes alone, the forefoot lift during the swing phase was 60-30% higher compared with the DAFO, particularly during the first and second tests. The lower displacement values obtained with the DAFO than with shoes was an important finding, because this demonstrates that the use of a DAFO could improve stability of the ankle and foot. However, the push-off phase improved with the DAFO compared with shoes alone, indicating that the DAFO did not fix the ankle too rigidly and allowed the heel and forefoot movements to tend towards a normal gait cycle (examples are shown in Figures A1.1).

These data provide evidence that the use of a DAFO may stabilize the ankle and foot, and provide a more symmetrical gait in stroke patients, particularly when walking problems are severe. Thus, terminal stance phase (heel rise) of stroke subjects was improved with the DAFO compared to the shoes-only condition, indicating that the DAFO did not fix the ankle too rigidly, thereby enabling the heel and forefoot movements to follow the pattern of a normal gait cycle. It was concluded that the findings of this pilot work suggested that DAFOs may affect some aspects of stroke patients' gait recovery (Uutela *et.al.*, 1996; Uutela *et.al.*, 1997).

Other modifications of methods during the main trial

Further observations were made during these studies with respect to the aims described earlier, which indicated the need for modification of the definitive protocol. These are described below in relation to 1) subject recruitment, 2) experimental procedures, and 3) gait tests. This section also describes methodological differences between the pilot and main phases implemented because of the availability of more modern instrumentation.

Subject B

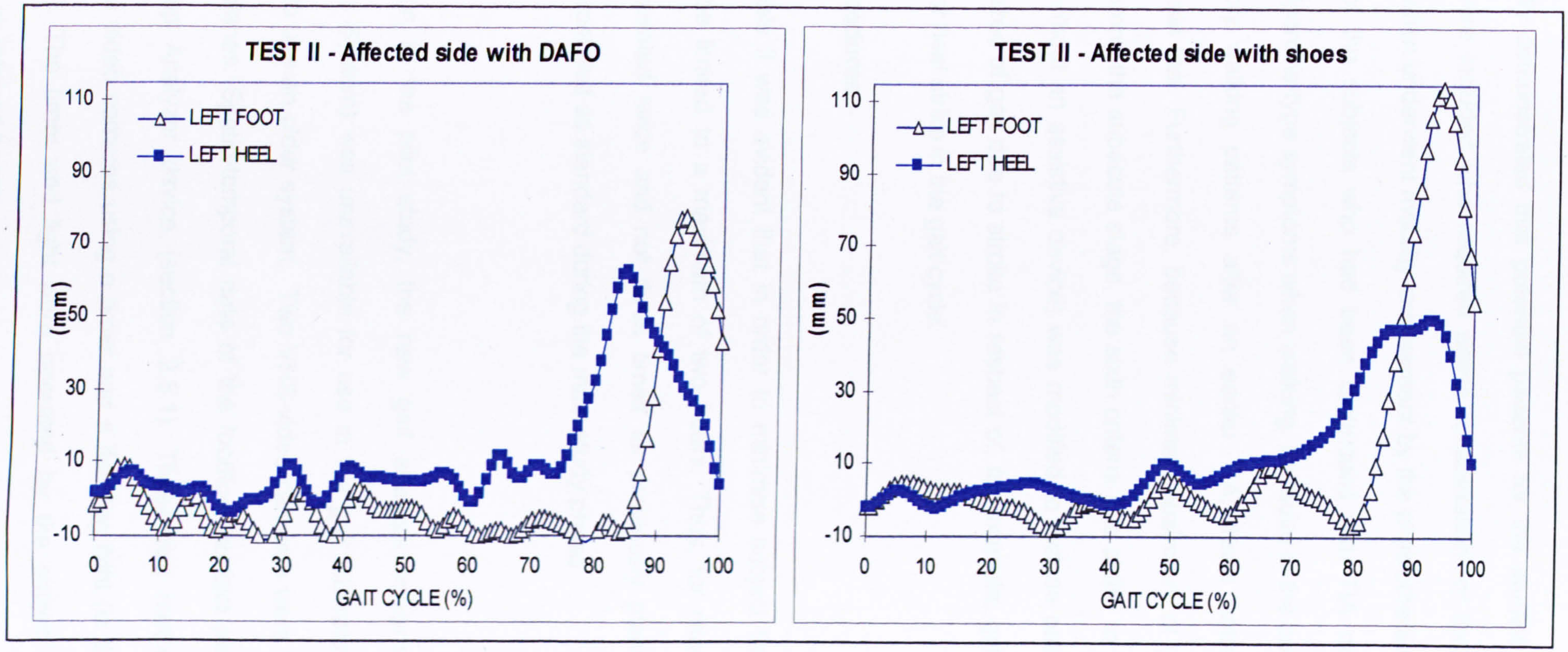


Figure A1.1 Foot (toe and heel markers) linear displacement motion, on the affected side, during one gait cycle with shoes and with DAFO in Test 2; the 100 % gait cycle is shown from a heel strike to heel strike.

1) Subject recruitment

The work successfully demonstrated that potential patients for the studies could be identified. Patients were included who required active rehabilitation for their mobility problems. However, when underwent mobility assessment by the physiotherapist, it was noted that several of the subjects who had been diagnosed with TIA might have exhibited earlier hemiparesis-type symptoms when walking. Because of the possibility of learning compensatory walking patterns after an earlier TIA, these patients were excluded from the main trial. Furthermore, because minimal impairment of gait is not adequately defined during the subacute stage, the sixth criteria (the ability to walk 5-10 metre or more with/without an assistive device) was modified to include patients who exhibited visibly impaired of gait due to stroke in respect of, for example, gait velocity, symmetrical rhythm, or heel strike in the gait cycle.

2) Experimental procedures

During the testing trials it was evident that in order to minimise subject fatigue, the testing time should be limited to a maximum of two hours. Thus, for example, the balance test was repeated twice and not three times as previously planned. This modification was incorporated as standard during the main study phase.

3) Gait tests

During data collection in the pilot study, the new gait analysis equipment (Ariel Performance Analysis System) was unavailable for use in the gait laboratory. It was therefore necessary to use an older system. Two VHS-video cameras were located in sagittal and frontal planes. Spatio-temporal data of the footfloor contact pattern was collected by the Step Analyzer device (section 2.5.1). These two methods were synchronised with the video cameras using a timer and a flashing light (in the field of view of the camera). The timer and light were operated by the subject's walking movements breaking an infrared beam.

After testing equipment synchronisation, it was apparent from viewing the recorded video picture that there was difficulty determining whether the timer and light were on or off. Consequently, preliminary data were collected with one camera placed on the sagittal plane, recording 2.5 metres of the total distance walked by the subject. The kinematic data were analysed later by Ariel Performance Analysing System obtained from the preliminary study using 2-D motion analysis when this instrument was operational. In the main trial the new synchronization system was available and used (section 2.5). After two testing trials it was found that data from the Step Analyzer were inaccurate due to technical faults, and consequently spatio-temporal data were not analysed from the 10-metre walkway, although gait velocity was calculated using the video-based data.

Conclusion

The pilot studies successfully achieved their aims concerning patient recruitment, safety, orthotic prescription and testing procedures, thereby facilitating appropriate modification during the main phase of the research, in order to provide a valid clinical assessment of the application of DAFOs with respect to stroke patients' rehabilitation. In addition, the preliminary work provided data suggesting that DAFOs may affect some aspects of stroke patients' physical recovery.

APPENDIX II

DAFO fabrication

Casting

Casting procedures were performed by the author and the orthotist at the University's School of Prosthetics and Orthotics or at the subjects' home. On arrival, the fabrication process and the casting materials to be used were described to the subject. In order to generate a negative cast of the subject's foot, the subject was seated comfortably on a standard office-type chair of rigid design, with their back kept straight and the knees and ankles flexed to approximately 90 degrees. The subject removed their sock and shoe from the side affected by the stroke and, when necessary, the affected foot was supported via a 'board' to maintain the foot/ankle in a neutral position (Figure A 2.1).

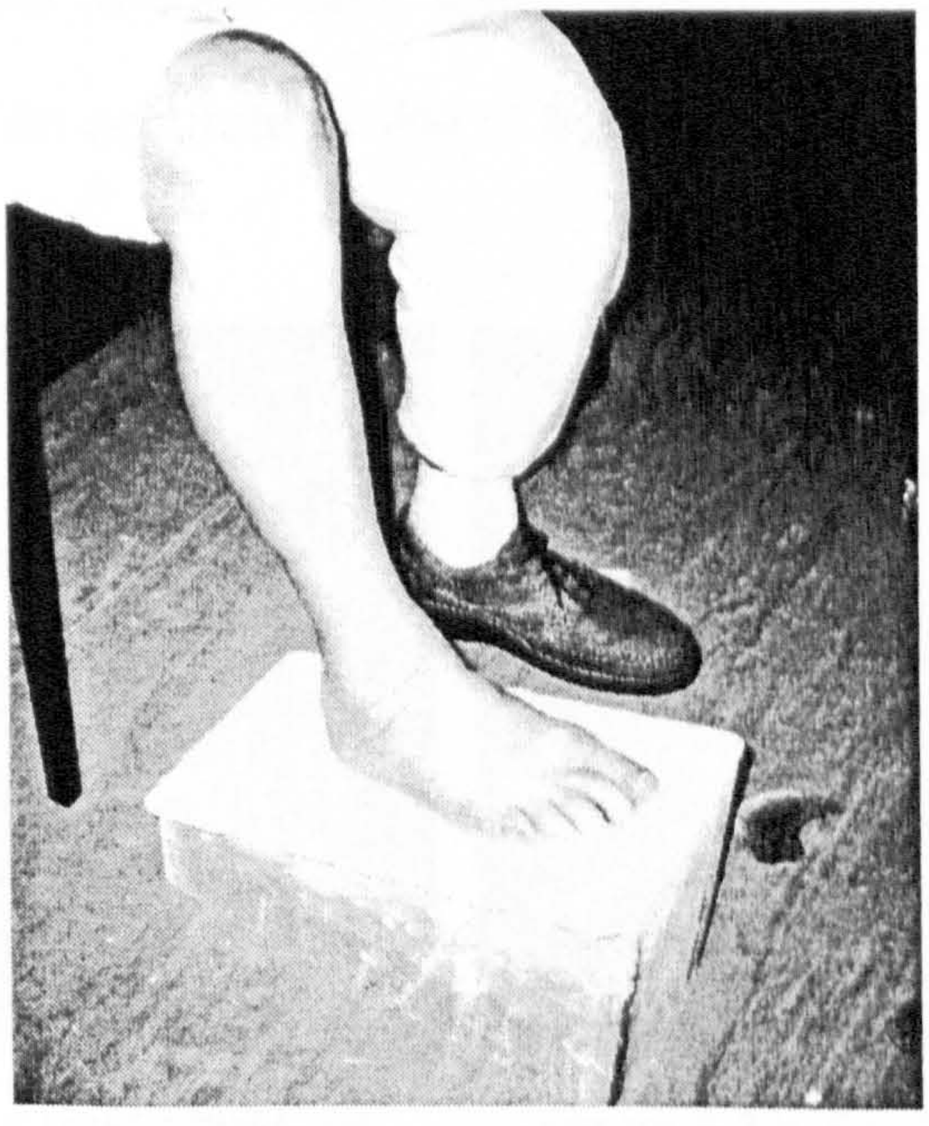


Figure A 2.1 Foot support during negative casting

In order to make a precise casting model of the subject's foot, an accurate weight-bearing outline of the foot (static) was first defined using carbon paper (Medical Gait Technology). Depending on the steadiness of the subject's balance, this procedure was done with the subject standing or sitting (Figure A 2.2). The outline of the foot was then used as a template to cut a 'pelite' sponge rubber board to the shape of the foot (Figure

A 2.3). Two layers of this board (each of 5 mm thickness) were stuck together adhesive tape, and the metatarsal and calcaneous areas were countersunk to a depth of 5 mm.

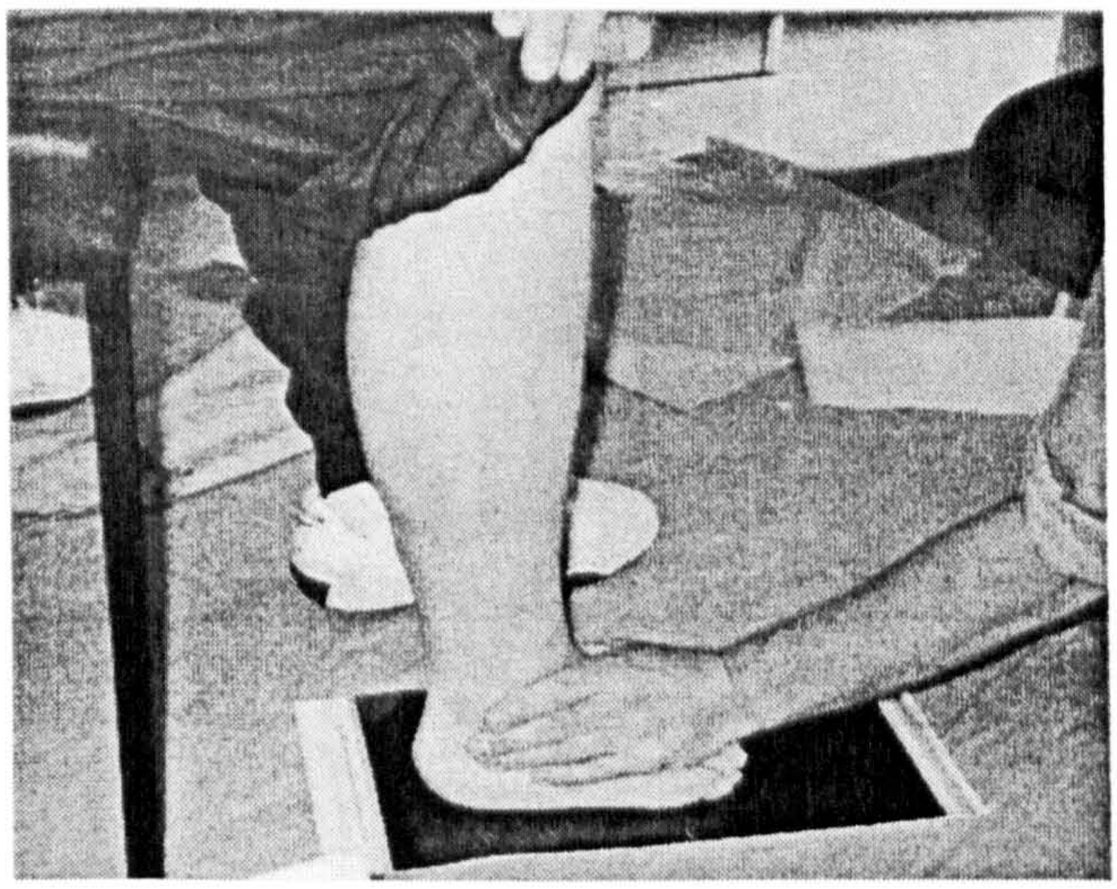


Figure A 2.2 Accurate outline of foot

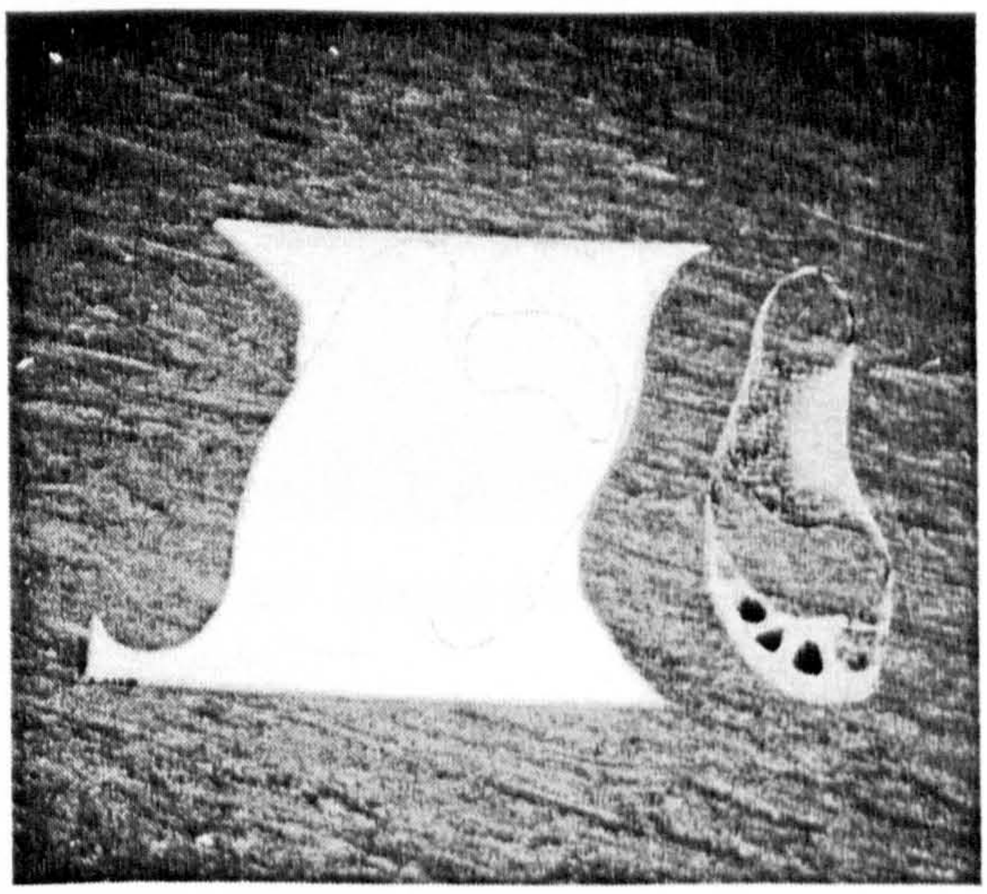


Figure A 2.3 Outline of foot is used as a template for a 'pelite' sponge rubber board

The board was then used to construct plaster 'build-ups' moulded under the longitudinal, peroneal and metatarsal arches and toes. This procedure formed the footboard negative, which defined an accurate profile of the arches (Figures A 2.4 and A 2.5).

Figure A 2.4 Constructing a plaster build-ups moulded under arches and toes

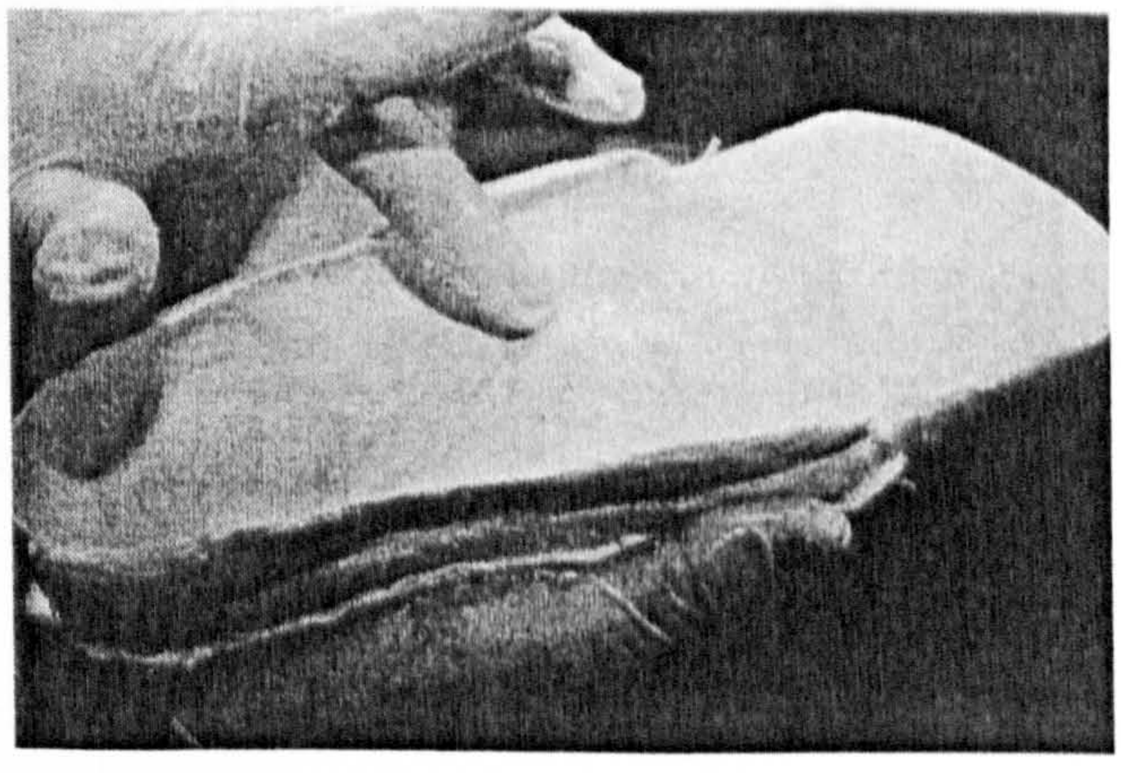


Figure A 2.5 Finalising footboard negative

The footboard negative was retained in position under the subject's foot by a layer of stockinet applied over the foot and ankle. Plaster was then wrapped around the foot, ankle and lower leg (Figure A 2.6 and A 2.7). During negative casting, the subject remained seated and, if necessary, the foot was kept in a neutral position by an angulated casting block (ankle in 0 - 20 degree flexion).

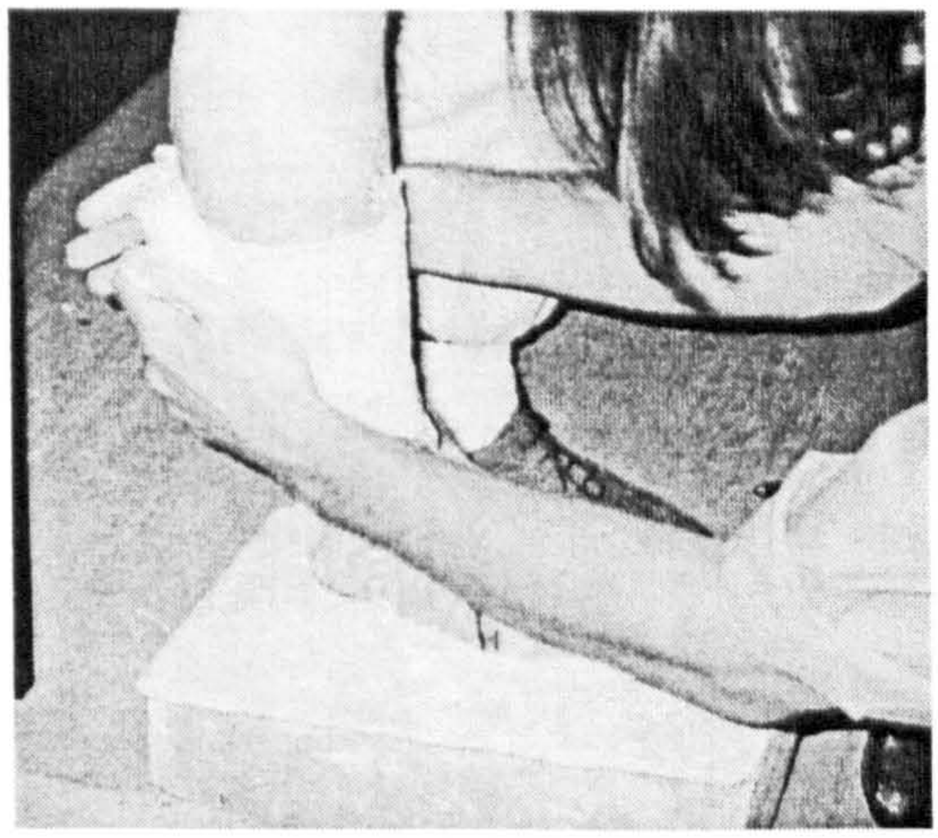


Figure A 2.6 Casting procedure around ankle

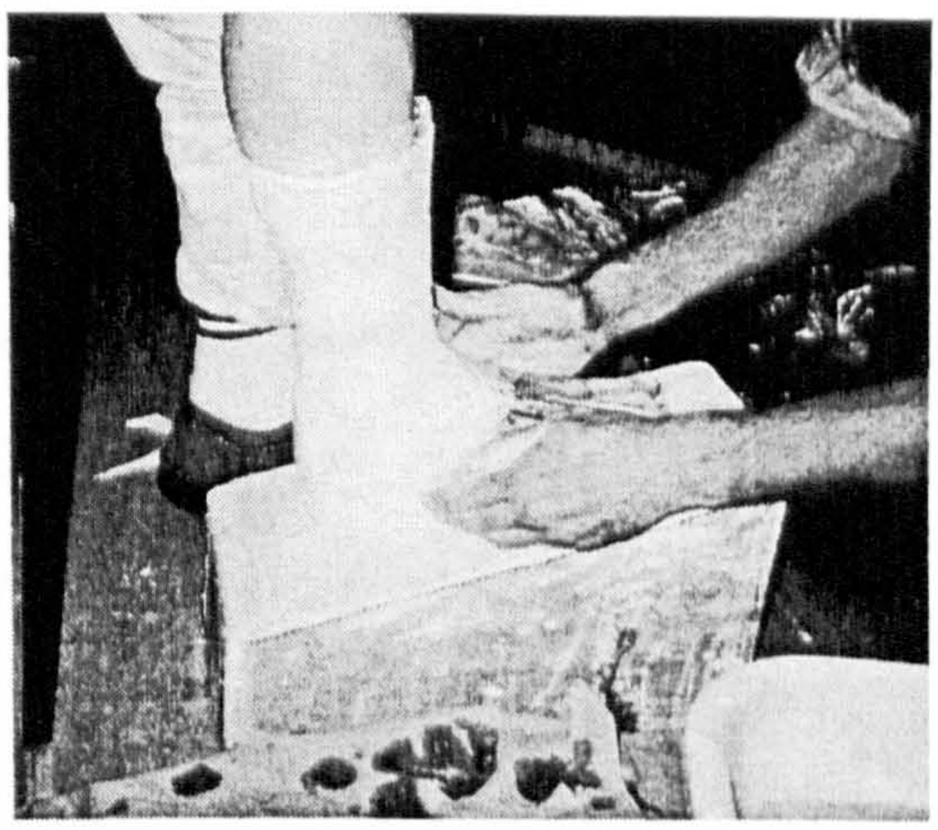


Figure A 2.7 Casting procedure around foot

After a few minutes, when the plaster dried, it was released gently by cutting the cast in half from the front. After releasing the cast was reassembled, and the final cast negative (Figure A 2.8) was packaged carefully and sent to the orthotic laboratory.

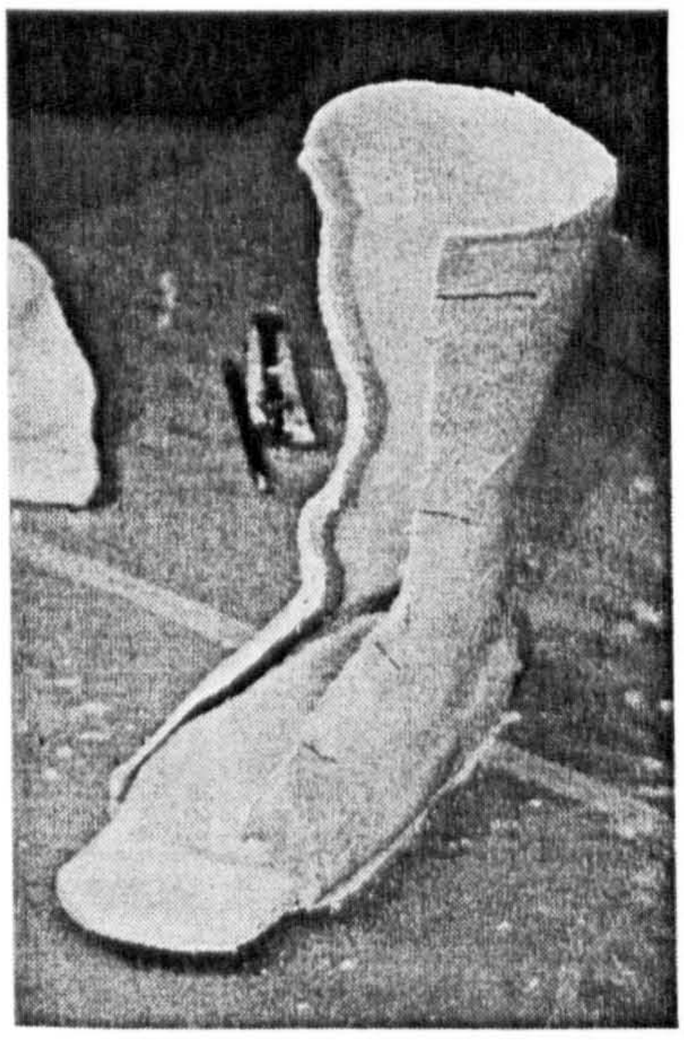


Figure A 2.8 Final cast negative – model

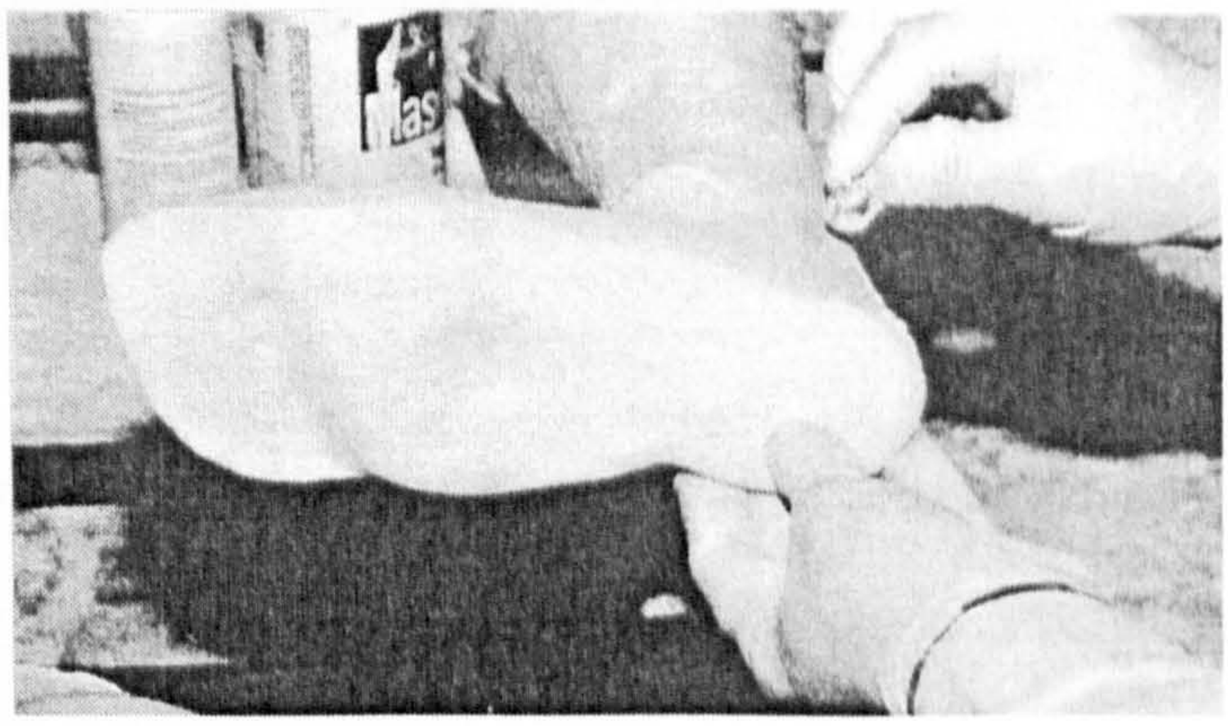


Figure A 2.9 Dried positive cast – smoothing

Assembly of the DAFO

DAFO fabrication was continued in the orthotic laboratory by the technician who firstly filled the negative cast with a soft 'Plaster of Paris' mash which, when dried, provided the positive cast. The positive cast was left at ambient room temperature for approximately 24 hours. The dried positive cast (Figure A 2.9) was rectified where

necessary and smoothed with 'Wet and Dry' papers (grades 280 and 400). The final stage of the casting procedures began with heating of homopolymer polypropylene board in an oven to at least 200 degrees centigrade. This heating stage made the material sufficiently soft and flexible to enable it to be stretched over the smoothed positive cast (Figure A 2.10 and A 2.11). As the homopolymer cools rapidly (within a few minutes) during the stretching stage, two technicians were required to work together in order to make the DAFO extremely thin and flexible (2-3 mm). Final trimming of the DAFO was carried the by hand and using purpose-built automated tools.

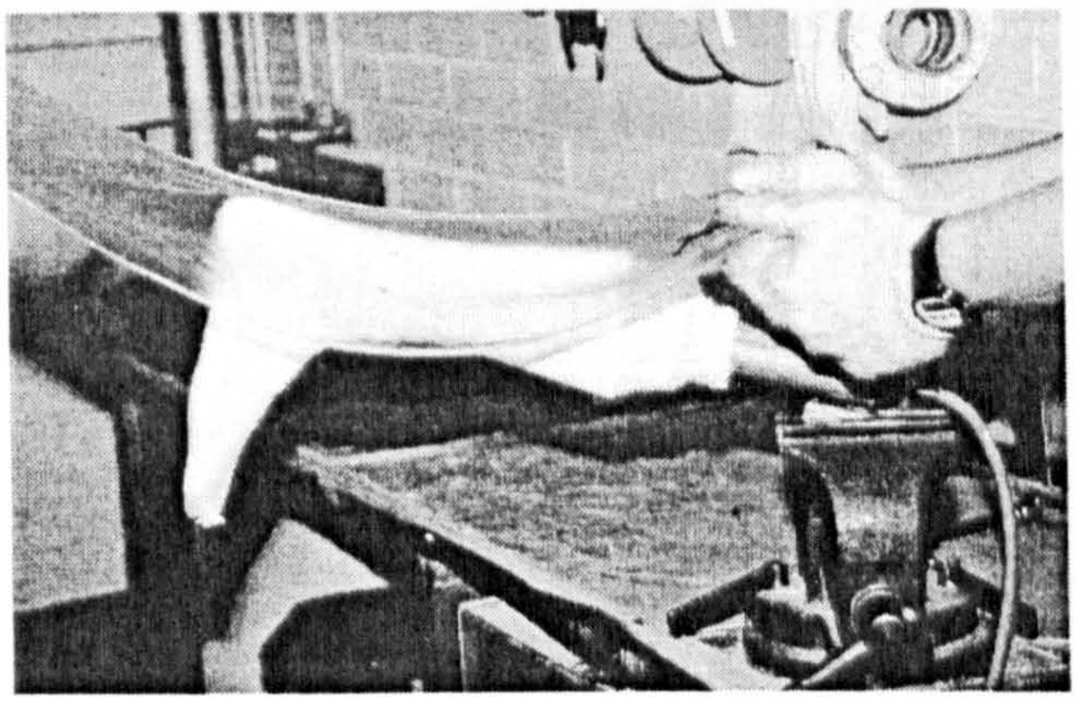


Figure A 2.10 Heated homopolymer polypropylene is stretched

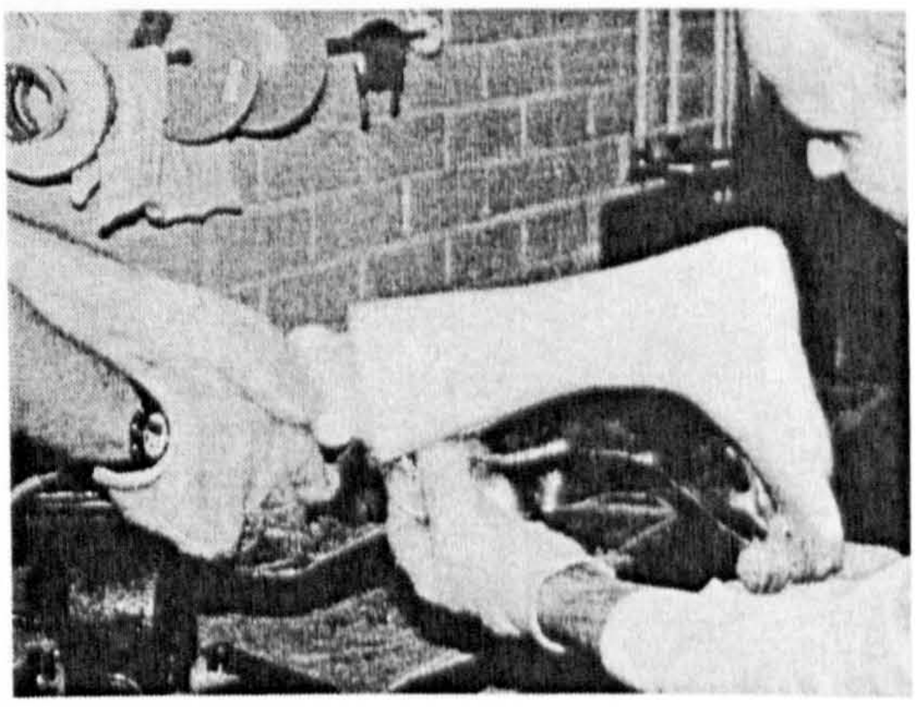


Figure A 2.11 Finalised stretching stage

In order to minimize frictional forces the homopolymer DAFO was padded inside with plastatzote (3 mm) over the bony prominences around the malleolus. Finally, Velcro straps were fixed over the dorsum of the foot and around the ankle (5 cm above the malleolei) to secure the orthosis in the correct position around the foot and ankle (Figure A 2.12). The subject was advised of a suitable shoe to be worn with the DAFO of casual design made from soft leather and usually one size larger than normally worn (Figure A 2.13).

Fitting

In total, 13 DAFOs were built during the research trial. Twelve subjects received a splint, 2 of which were excluded from the trial due to personal or health reasons. One subject

experienced problems with pressure around the ankle (malleoulus) area with their DAFO and a second splint was constructed.

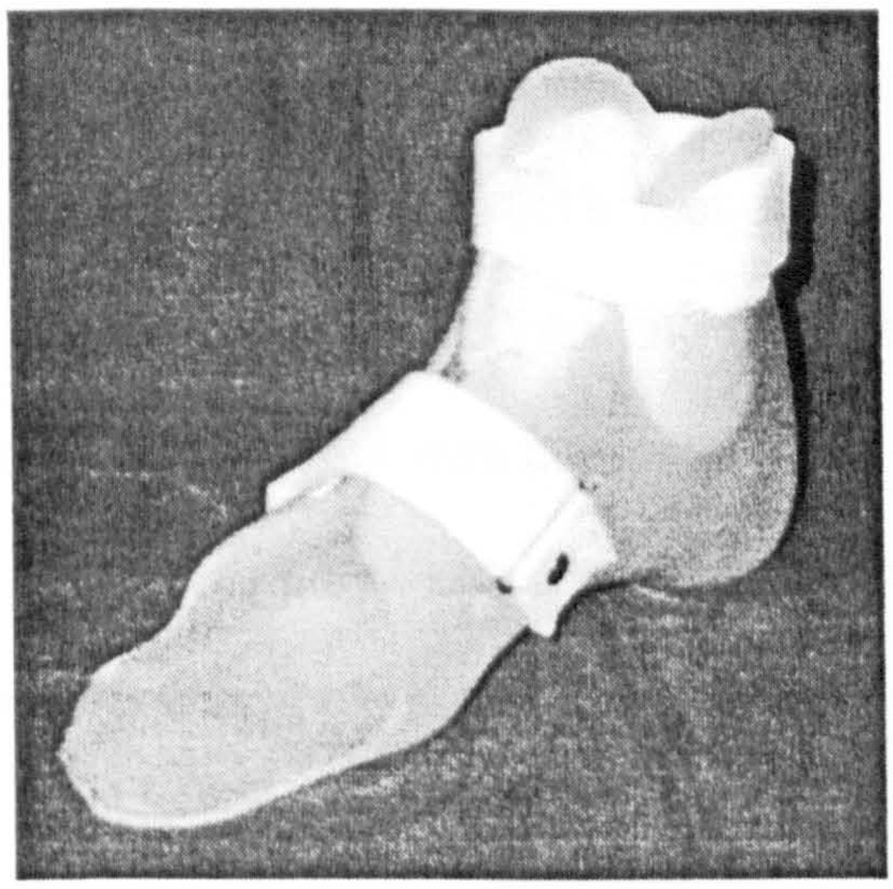


Figure A 2.12 DAFO with fixed Velcro straps

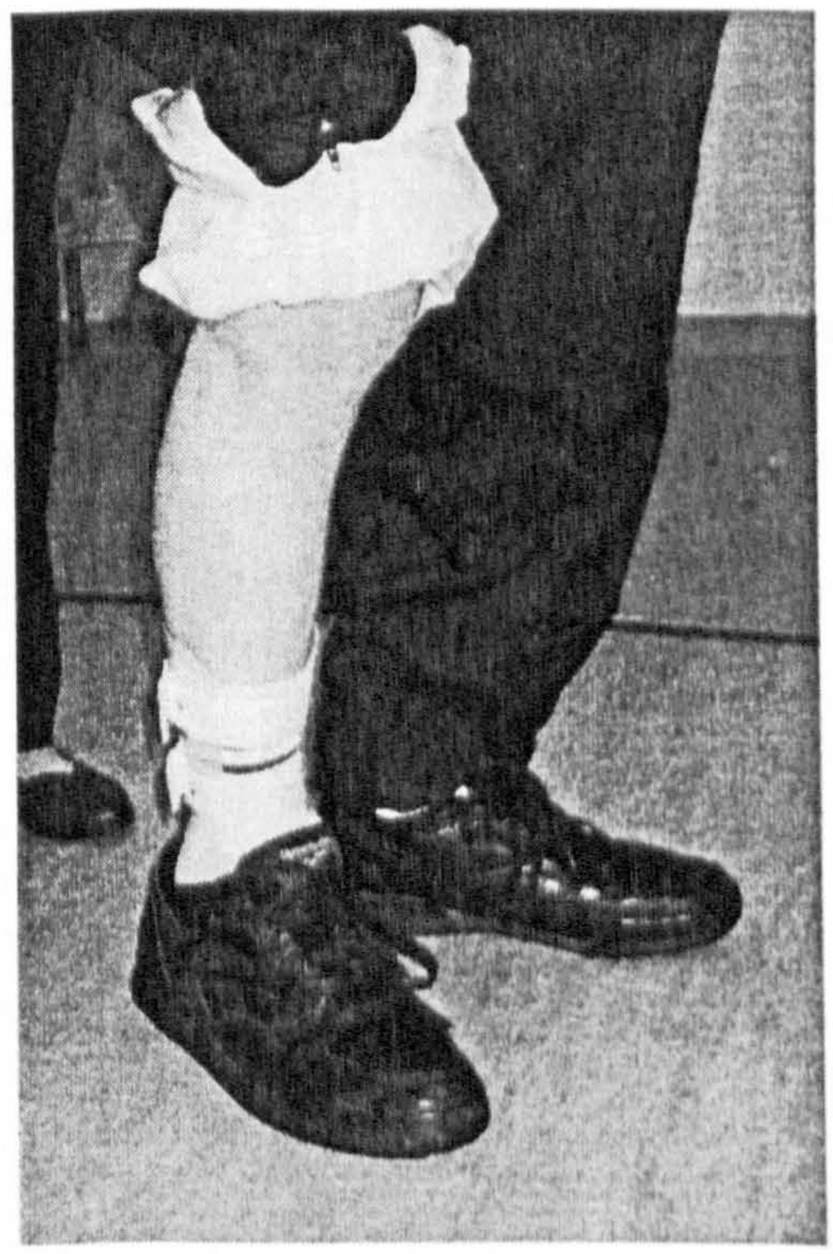


Figure A 2.13 DAFO fitting

During the 3 months experimental follow-up, a questionnaire was used to determine whether the subjects of the experimental group required the orthotist to adjust or modify the DAFO or shoes after each testing session. Ten subjects provided answers to the question set; the results are presented in Table A 2.1.

Table A 2.1

Orthotist required?	Answered no	Answered yes
Test I	7	3
Test II	8	2
Test III	9	1

In test I one subject's Velcro strap around the ankle area required modification and two subjects experienced pressure problems using the splint, one on the little toe and the other on the malleoulus. To correct the first problem the orthotist trimmed the DAFO around the toe area. The second subject's pressure problems were found to be caused by swelling of the subject's foot-ankle area unrelated to the use of the DAFO. The swelling was alleviated following treatment provided by the subject's GP and, after one month, a new splint was prescribed and built. In Test II, the two subjects who requested to see the orthotist required Velcro strap alterations; similar minor adjustments were made for the single subject in Test III.

DYNAMIC ANKLE-FOOT ORTHOSIS - CASTING, FABRICATION AND FITTING:

SUBJECT DETAILS:

NAME:	DOB:	HOS.NO:
ADDRESS:		
TEL:		

GENDER: F / M

SIDE OF WEAKNESS: L / R

DG:
CT:

PREVIOUS TIA: NO _____/ YES _____

DATE OF ADMISSION: _____ BI: _____

DATE OF DISCHARGE: _____ BI: _____

OTHER ILLNESESS:

SOCIAL DETAILS: MARRIED _____ SINGLE _____

IN EMPLOYMENT _____ RETIRED _____

RESIDENCE:

LIVING ALONE _____ WITH FAMILY/ FRIENDS _____

NAME: _____ **DATE:** _____

DATE OF ADMISSION TO STUDY:

CASTING / THE MODEL OF DAFO:	**COMMENTS:**

FABRICATION (Materials, EVA, straps, etc.)

NAME: _____ **DATE:** _____

FITTING:
DATE:
CHANGES:
COMMENTS:

FITTING:
DATE:
CHANGES:
COMMENTS:

INFORMATION FORM

HOW TO USE DYNAMIC ANKLE-FOOT ORTHOSIS

Correct fitting of the splint

- Put on your sock
- Fit the DAFO on the foot and tighten the straps
- Wear the shoes which you have chosen with the physiotherapist

Use the splint during the first few days in two hours periods and check 2 - 3 times a day the condition of the skin of the foot and ankle: - are there red or dark marks or is there any pain ?

If the DAFO splint feels good, continue to use the orthosis for half a day over the next two days.

If the splint continues to feels good, you can now start to wear the DAFO all day while you are up, walking, doing house work or even just relaxing watching TV.

Every morning, look at the skin of the foot and ankle, before you getting dressed, and in the evening before you go to bed. If you feel pain in any area under the DAFO, or find marks on the skin, please, contact the project physiotherapist Anne Uutela, tel. 0161-736 6541/ extension 817, or your local nurse or physiotherapist.

During this research trial we will test if this splint affects your walking and standing balance and consequently your everyday life after stroke. The next few weeks are very important in order to shows us if the DAFO splint has effects. This will only be possible if you wear your special splint every day and inform us of any problems.

Thank you very much for your co-operation!

Anne Uutela

APPENDIX III

Information sheet, evaluation forms, and muscle test and results **page**

1. Patients information sheet 336
2. Patient's opinion to use of orthoses 338
3. Nottingham extended ADL scale 342
4. Rivermead Motor Assesment ; Functional scale 343
5. Rivermead Motor Assesment ; Leg and Trunk scale 344
6. Muscle strength form and results 345
7. Gait evaluation form 348

DAFO project 1995-98, University of Salford

Patients Information Sheet

We would like to offer you the opportunity to take part in a research study run at Ladywell and Hope Hospitals and the School of Prosthetics and Orthotics in the Salford University. The purpose of the study is to see whether a new device (called a Dynamic Ankle-Foot Orthosis or DAFO for short) helps people who have had a stroke to walk.

The DAFO is a simple device that fits into the shoe and supports the foot and ankle. We hope that this may help balance and walking. As we do not know whether it will in fact be helpful, we are giving some patients the DAFO along with their therapy while other patients are having only therapy. Both groups of patients will be picked at random; however which group you are in, your rehabilitation will continue as normal. As we do not know whether the DAFO will be helpful, if you are allocated to the group that does not have the DAFO this may not necessarily be a disadvantage. This study should give us important information about the effect of these splints and how to use them in rehabilitation.

Your standing balance and walking will be tested three times at the School of Prosthetics and Orthotics during the next three months, each session lasting about an hour. The procedure will consist of three tests. The first is a 5 metre walking-test to evaluate leg movements using video and small sensors placed in the shoes. The second test involves standing body sway. The final test will assess your activities of everyday life using a simple questionnaire.

We will provide private transport to the university and for your return home.

Please do not hesitate to ask if you have any questions regarding the testing procedures or any other part of the research. If you are happy with the information and agree to participating in the research, we will ask you to sign a consent form. At any point you will be free to withdraw yourself from the study, without having to give a reason and without affecting any medical care.

We are very grateful for your consideration.

DAFO project 1996-98, University of Salford.

Patients' opinion of use of the orthoses:

Name:_____ **D.O.B.** _____ **Date:** _____

1. Do you use a wheelchair? NO_____/ YES_____.

How many hours per day_____.

2. Do you use other walking aids? NO____/YES____, Inside/ outside.

3. Do you need help to put on the orthosis? NO____/ YES____

4. Do you need help to take off the orthosis? NO____/YES____

5. If you do, who helps you?

_____

6. Do you need help to get dressed? NO____/YES____.

7. How many hours do you use the orthosis during daytime?

7a. always when you are walking? NO____/ YES____.

7b. always when you are standing? NO____/YES____.

7c. always when you sitting? NO____/YES____.

7d. in the mornings? NO___/ YES___, _____hours.

7e. in the evenings ? NO___/YES___, _____hours.

8. What is your approximate walking distance?

8a. Inside? _____ meters.

8b. Outside on the street? _____ meters.

8c. Outside in the countryside? _____meters.

For next fife questions we will ask your opinion of the use of orthoses by choosing the number which best describes your experience.

4= No problems, comfortable.

3= Mostly comfortable.

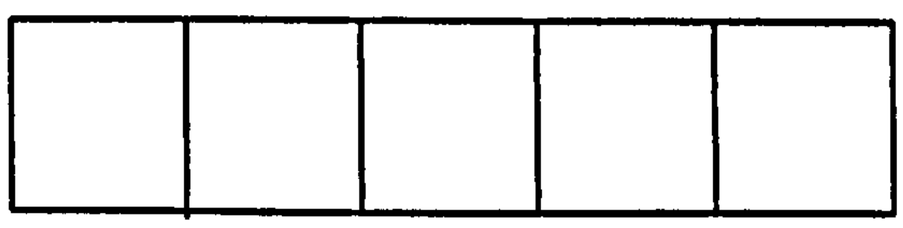
2= Sometimes difficult.

1= Always difficult.

0= Always very difficult/ uncomfortable.

9. How do you find putting on and take off the DAFOs ?

0 1 2 3 4



10. Would you describe more your answer in the question 9 ?

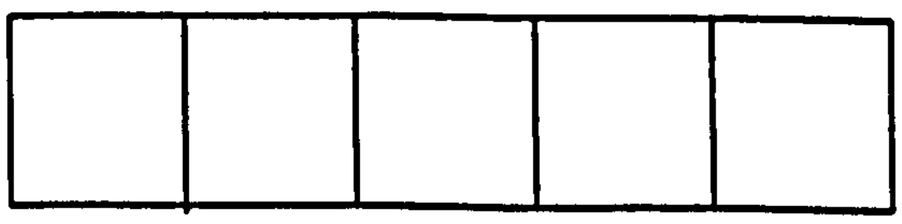
_____

_____

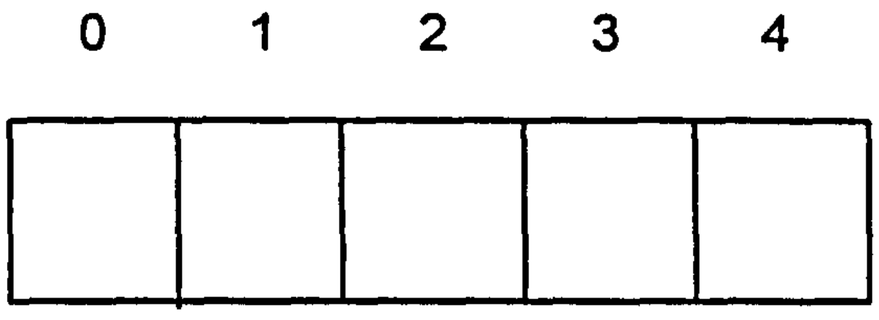
_____

11. How does the DAFO feel ?

0 1 2 3 4



12. How does it feel to walk with the DAFO ?



13. What do you think are the main problems with the DAFO ?

14. What do you think are the best/ positive things for using the DAFO ?

15. Has you received a physio or/and occupational therapist since starting to wear the DAFO ? NO ____/ YES_____.

15a. at home (community, private etc.)

15b. at the hospital out-patient clinic

15c. Other

16. How many times per week?

17. Do you think you need to see the orthotist ? NO ____/ YES _____.

If YES, why ?

_____

_____

_____

_____

DAFO project 1995-98, University of Salford.

Nottingham Extended ADL Index

Name/code:_____ **Date:**_____ **Total :** _____

Answers:	Not at all	With help	Alone with difficulty	Alone easily
Scores 0 - 3	(0)	(1)	(2)	(3)
Questions:				
Mobility - do you:				
1. walk around outside?	☐	☐	☐	☐
2. climb stairs?	☐	☐	☐	☐
3. get in and out of the car?	☐	☐	☐	☐
4. walk over uneven ground?	☐	☐	☐	☐
5. cross roads?	☐	☐	☐	☐
6. travel on public transport?	☐	☐	☐	☐
In the kitchen - do you:				
1. manage to feed yourself?	☐	☐	☐	☐
2. manage to make yourself a hot drink?	☐	☐	☐	☐
3. take hot drinks from one room to another?	☐	☐	☐	☐
4. do the washing up?	☐	☐	☐	☐
5. make yourself a hot snack?	☐	☐	☐	☐
Domestic tasks - do you:				
1. manage your own money when you are out?	☐	☐	☐	☐
2. wash small items of clothing?	☐	☐	☐	☐
3. do your own shopping?	☐	☐	☐	☐
4. do a full clothes wash?	☐	☐	☐	☐
Leisure activities - do you:				
1. read newspapers or books?	☐	☐	☐	☐
2. use the telephone?	☐	☐	☐	☐
3. write letters?	☐	☐	☐	☐
4. go out socially?	☐	☐	☐	☐
5. manage your own garden?	☐	☐	☐	☐
6. drive a car?	☐	☐	☐	☐

DAFO **project** **1995-98, University of Salford.**

Rivermead Motor Assessment - functional test

General instructions:
Score 1 if patient can perform activity, 0 if he cannot. Three tries are allowed, and proceed to the next. Give general encouragement, but no feedback or corrects. Repeat instructions and demonstrate them to the patient if necessary.
All exercises to be carried out independently unless otherwise stated.

Name/code_____ **Date**_____

Gross function section **score**

1. Sit unsupported
   Without holding on, on edge of bed, feet unsupported. ☐
2. Lying to sitting on side of bed
   Using any method. ☐
3. Sitting to standing
   May use hand to push up. Must stand up in 15 sec and stand for 15 sec, with an aid if necessary. ☐
4. Transfer from wheelchair to chair towards unaffected side
   May use hands. ☐
5. Transfer from wheelchair to chair towards affected side
   May use hands. ☐
6. Walk 10 m indoors with an aid.
   Any walking aid. No stand-by help. ☐
7. Climb stairs independently
   Any methods. May use banister and aid - must be full flight of stairs. ☐
8. Walk 10 m indoors without an aid
   No stand by help. No caliper, splint or walking aid. ☐
9. Walk 10 m, pick up beanbag from floor, turn and carry back
   bend down any way, may use aid to walk if necessary. ☐
   No stand-by
   help. May use either hand to pick up bean back.
10. Walk outside 40 m
    May use walking aid, caliper or splint. No stand-by help. ☐
11. Walk up and down four steps
    Patient may use an aid if he would normally use one, but may not hold on to rail. This is included to test ability to negotiate curb or stairs without a rail. ☐
12. Run 10 m
    Must be symmetrical. ☐
13. Hop on affected leg five times on the spot
    Must hop on ball of foot without stopping to regain balance. ☐
    No help with arms.

Gross functional total ☐

DAFO project 1995-98, University of Salford.

Rivermead Motor Assessment ...

Leg and trunk **Score**

1. Roll to affected side
   Starting position should be lying, not crook lying. ☐
2. Roll to unaffected side
   Starting position should be lying, not crook lying. ☐
3. Half-bridging
   Starting position - half-crook lying. Patient must put some weight through affected leg to lift hip on affected side. ☐
   Therapist may position leg, but patient must maintain position even after movement is completed.
4. Sitting to standing
   May not use arms - feet must be flat on floor - must put weight through both feet. ☐
5. Half-crook lying; lift affected leg over side of bed and return it to same position. ☐
   Affected leg in half-crook position. Lift leg off bed on to support; for example, box, stool, floor, so that hip is in neutral and knee at 90 degrees while resting on support. Must keep affected knee flexed throughout movement. Do not allow external rotation at hip. This tests control of knee and hip.
6. Standing, step unaffected leg on and off block ☐
   Without retraction of pelvis or hyperextension of knee. This Tests knee and hip control while weight bearing through the unaffected leg.
7. Standing, tap ground lightly five times with unaffected foot ☐
   Without retraction of pelvis or hyperextension of knee. Weight Must stay on affected leg. This again test knee and hip control While weight bearing through the affected leg but is more difficult Than in 6.
8. Lying, dorsiflexion affected ankle with leg flexed. ☐
   Therapist may hold affected leg in position, knee at 90 degrees. Do not allow any inversion. Must have half range of movement of unaffected foot.
9. Lying, dorsiflex affected ankle with leg extended ☐
   Same conditions as in 8, with leg extended. Do not allow any inversion or knee flexion. Foot must reach plantigrade (90).
10. Stand with affected hip in neutral position, flex affected knee ☐
    (45 degrees +)
    Therapist may not position leg. This is extremely difficult for most hemiplegic patients, but is included to assess minimal dysfunction.

Leg and trunk total ☐

DAFO project 1996-98, P & O, University of Salford.

MUSCLE STRENGTH

Modified from The Medical Research Council (MRC) scale

NAME: _____ **HOS.NO.** _____ **DATE:** _____

0 = NO MOVEMENT
1 = PALPABLE CONTRACTION, BUT NO VISIBLE MOVEMENT
2 = MOVEMENT BUT ONLY WITH GRAVITY ELIMINATED
3 = MOVEMENT AGAINST GRAVITY
4 = MOVEMENT AGAINST RESISTANCE, BUT WEAKER THAN OTHER SIDE
5 = NORMAL POWER

		RIGHT SIDE	LEFT SIDE
ANKLE:	FLEX	_____	FLEX _____
	EXT	_____	EXT _____
KNEE:	FLEX	_____	FLEX _____
	EXT	_____	EXT _____
HIP:	FLEX	_____	FLEX _____
	EXT	_____	EXT _____

COMMENTS: (spasticity, pain, stiffness, etc.)

Results from the muscle test (scale 0 – 5)

Experimental group:

	ANKLE	KNEE	HIP
D01	1-2 / 2-3	3+ / 3+	2-3 / 1-2
D02	2/ 2+	3+ / 3	3-4 / 2-3
D03	2-3 / 3	3- / 2-3	2 / 2
D04	2-3 / 4	2- / 2-3	2-3 / 2+
D05	0 / 0	3 / 2-3	3-4 / 3-4
D06	2+ / 3-4	3-4 / 4	3-4 / 3-4
D07	2 / 2	3 / 3-	3-4 / 3-
D08	1 / 1-2	2-3 / 2	2-3 / 3
D09	0 / 0	1 / 1	2 / 1-2
D10	1-2 / 0	1-2 / 0+	2 / 0-1
D11	0+ / 0+	1 / 1	4 / 4
Average	**1.5 / 1.7**	**2.2 / 2.3**	**2.9 / 2.5**

Results from the muscle test (scale 0 – 5)

Control group:

	ANKLE	KNEE	HIP
C01	3-4 / 3-	4 / 4	4 / 4
C02	3+ / 3+	3-4 / 4	4-5 / 3
C03	2+ / 3-4	3-4 / 4	3-4 / 3-4
C04	3 / 3	4-5 / 4-5	3-4 / 4-5
C05	2-3 / 4	4 / 4	4 / 3
C06	0 / 1	2 / 2+	4 / 2+
C07	1+ / 2	3+ / 4-	3-4 / 4-5
C08	3+ / 3+	3 / 2+	3 / 3-4
C09	4 / 2+	3- / 3-	5 / 3+
C10	1-2 / 1-2	2 / 3+	3 / 2
C11	2+ / 3-	3 / 2+	2 / +
Average	**2.3 / 2.7**	**3.3 / 3.4**	**3.6 / 3.1**

DAFO project 1995-98, P & O, University of Salford.

GAIT EVALUATION

NAME:	DOB:	Hos No:
ADDRESS:		
TEL:		

PHYSIO/OT:

DIAGNOSIS:

STANDING ABILITY:

WALKING ABILITY:

DAFO project ...

STANCE PHASE:	ANKLE	KNEE	HIP	TRUNK
INITIAL CONTACT/ **(IC)**				
LOADING RESPONCE / **(LR)**				
MID-STANCE/ **(MST)**				
TERMINAL STANCE/ **(TST)**				
PRE-SWING/ **(PS)**				

SWING PHASE:	ANKLE	KNEE	HIP	TRUNK
INITIAL SWING				
MID-SWING				
TERMINAL-SWING				

APPENDIX IV

A 3.1 Formulae used to extract dependent measures from force and spectral data as described by McClenaghan *et. al.* (1995)

$$f_k = k/T, \quad k = 0,N/2$$

$$f_{mean} = \frac{\sum_{k=1}^{N/2} f_k S_k}{\sum_{k=1}^{N/2} S_k}$$

$$f_{sd} = \sqrt{\frac{\sum_{k=1}^{N/2} (f_k - f_{mean})^2 S_k}{\sum_{k=1}^{N/2} S_k}}$$

$$s = \frac{\left(\frac{N}{2}+1\right)\sum_{k=1}^{N/2}(\log S_k \ \log f_k) - \sum_{k=1}^{N/2}\log f_k \sum_{k=1}^{N/2}\log S_k}{\left(\frac{N}{2}+1\right)\sum_{k=1}^{N/2}\log^2 f_k) - \left(\sum_{k=1}^{N/2}\log f_k\right)^2}$$

Symbol	Description	Unit of measure
N	Number of elements in force vector (512)	count
F_k	Force vector (m-l and a-p)	Hz
f_k	frequency	Hz
S_k	Power spectrum	N^2/Hz
fmean	Centroid frequency	Hz
fsd	Frequency dispersion	Hz
S	Slope	--

8 ABSTRACT AND PUBLICATIONS

Uutela A, Howe T, Melia J, Bowker P. (1996) The effect of Functional Ankle-Foot Orthoses on balance and gait pattern in stroke patients: a preliminary study. European Journal of Neurology, 3, Suppl. 2.

Uutela A, Howe T. (1997) Effect of Dynamic Ankle-Foot Orthoses on stroke patients' balance and gait. The Annual Congress of the Chartered Society of Physiotherapy. Edinburgh 19-21 September. Abstract.

Uutela A, Bowker P. (1998) Effect of Dynamic Ankle-Foot Orthoses on stroke patients' balance – A randomised trial. IXth World Congress of The International Society for Prosthetics and Orhtotics. The Netherlands, June 28 – July 3. Abstract and oral communication.

Uutela A, Bowker P. (1998) Effect of Dynamic Ankle-Foot Orthoses on stroke patients' gait. IXth World Congress of The International Society for Prosthetics and Orthotics. The Netherlands, June 28 – July 3. Abstract and oral communication.

Uutela, A, Bowker, P. (2003) The Effect of Dynamic Ankle-Foot Orthoses on the Gait of Stroke Patients. 14th International World Physical Therapy congress, 7 - 12 June 2003, Barcelona, Spain. Abstract and oral communication.