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The effects of high custom made shoes on gait characteristics and patient satisfaction in hemiplegic gait^{☆,☆☆}

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ABSTRACT

Objective: To determine the effects of a temporary high custom made orthopaedic shoe on functional mobility, walking speed, and gait characteristics in hemiplegic stroke patients. In addition, interference of attentional demands and patient satisfaction were studied.

Design: Clinical experimental study.

Setting: University Medical Centre.

Participants: Nineteen stroke patients (12 males; mean age 55 years (standard deviation (SD) 10 years); mean time post onset 3.6 months (SD 1.4 months)) with a spastic paresis of the lower extremity.

Main outcome measures: Functional mobility was assessed with the timed up and go test, walking speed and gait characteristics were measured with clinical gait analysis and performed with and without a verbal dual task. Patient satisfaction was determined with a questionnaire.

Results: Walking with the high orthopaedic shoe resulted in improved functional mobility (22%; $p < .001$), walking speed (37%; $p < .001$) and gait characteristics compared to walking with normal shoes. The dual task interfered with functional mobility during walking. The interference was equally big for normal shoes as for the orthopaedic shoe. Patients evaluated walking with the high orthopaedic shoe as an improvement ($p < .001$). An average of 84% reported improvements in foot lifting, swing progression, taking weight, confidence while walking, safety, walking distance and walking speed.

Conclusion: In the early recovery phase after stroke, when regaining walking ability, a temporary high orthopaedic shoe can improve hemiplegic gait, even with dual task interference.

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1. Introduction

Although 70% to 80% of all stroke patients regain an independent walking function [1–3], only 30% of these patients reach a normal walking speed and walking distance [4]. To improve hemiplegic gait, different ankle foot orthoses (AFO) are prescribed [5]. Studies on the effect of AFO's in hemiplegic gait

reveal conflicting evidence [6–12]. The current study examines the effects of a temporary high orthopaedic shoe on hemiplegic gait. A high orthopaedic shoe is a custom made shoe with a stiff leg made of carbon fibres or a semi-stiff leg made of ercoflex (Fig. 1). The ankle and knee are stabilised and the foot is positioned to facilitate walking. Patients with severe equinovarus deformity and severe hyperextension of the knee in stance phase are likely to benefit from this type of shoe. Often it is prescribed in a subacute phase in which the patient is not able to walk independently without an orthosis and/or if it is not yet clear if, or what kind of orthosis will be needed in the long run. The custom made shoe facilitates ambulation during and outside physical therapy. The advantages of high orthopaedic shoes are the capacity to resist high forces, optimal fitting and a production time of less than two weeks.

A number of studies have found that a verbal dual-task decreases walking ability in stroke patients [13,14]. Due to a loss of automaticity, walking has become attention demanding [15,16]. Dual-task interference may explain why walking performance in a less demanding and safe clinical setting does not necessarily

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^{**} The manuscript submitted does not contain information about medical device(s).

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Fig. 1. A temporary high orthopaedic shoe with a stiff leg made of carbon.

predict performance in daily life situations. As the custom made shoe is meant to be worn outside therapy sessions we were interested in potential dual task interference.

The present study aims to compare walking with a temporary high orthopaedic shoe versus walking with normal shoes in stroke patients with respect to (1) functional mobility, walking speed and gait characteristics, (2) the effect of a verbal dual task on walking, (3) patient satisfaction towards walking.

2. Methods

2.1. Subjects

A convenience sample of 19 stroke patients treated in inpatient rehabilitation facilities in Rotterdam was recruited. Inclusion criteria were aged 18 years or older, a first unilateral hemorrhagic or ischemic stroke resulting in a hemiplegia with a spastic paresis of the leg (Modified Ashworth Scale score of 1 or more of the plantarflexors of the foot). Patients had to be able to walk at least 20 m in normal shoes with or without walking aids or supervision and needed to be able to follow simple instructions. Excluded were patients with other neurological, orthopaedic or vascular diseases that could influence walking ability. All patients gave written permission to participate in the study and ethical approval was obtained.

2.2. Experimental set-up

To prevent pressure sores the time in which the orthopaedic shoes are worn (also outside therapy sessions) is gradually increased during two weeks. In these two weeks the patient practiced about 50% of the time with the normal shoes and 50% with the orthopaedic shoe.

Functional mobility and gait characteristics were determined while wearing a high orthopaedic shoe (and a normal shoe corrected for sole thickness on the non-affected side) and normal shoes, with and without a verbal dual-task. The order of the conditions was set after a nested randomization for type of shoes, and secondly dual task. After a practice session, two 5 min trials each of each condition were performed. Patients were allowed to use walking aids, but no personal assistance was given. To guarantee safety, one of the investigator walked just behind the patient. In between conditions, 5 min rest was taken on a chair. In total the measurement on the walkway took 45 min per patient.

Functional mobility was assessed with the timed up and go test (TUG) [17,18]. Walking speed and gait characteristics were assessed in a clinical gait laboratory, and patient satisfaction with a questionnaire.

2.3. TUG

The TUG is a reliable and sensitive test measuring improvements in walking related abilities in stroke patients [17,18]. The TUG measures the time needed to rise from a chair, walk 3 m, turn around, walk back to the chair and sit down again. A chair with a seat height of 0.45 and an armrest height of 0.66 m was used for all patients. Patients were allowed to use the armrests for rising.

2.4. Gait analysis

In a clinical gait analysis laboratory, patients walked along a 9 m walk way and were instructed to walk at comfortable walking speed. Two digital cameras (shutter time 1/250 s, diaphragm 15 dB, frame frequency 50 Hz) were used to capture a sagittal and a dorsal view of the affected side. Passive markers with a diameter of 0.5 cm were attached to the major trochanter, the lateral epicondylus, the lateral malleolus, and to the calcaneus. The marker set was not of previously validated format. The location of the markers were digitalised (50 Hz, unfiltered) and transformed to coordinates of a sagittal and frontal plane (SIMI motion, SIMI Reality Motion Systems GmbH, Unterschleissheim, Germany). From the position of the markers 2D kinematics were calculated for the 2 × 2D space calibrated middle 3 m of the walk way.

Step length, stance duration, cadence and walking speed were calculated from the sagittal spatiotemporal information of the lateral malleolus. Clearance of the affected leg was determined by measuring the distance between the lowest part of the sole and the floor in mid swing. Step width was determined from the distance between the markers in the frontal plane on the dorsal sides at the level of the tuber calcanei of the right and left calcaneus. The knee flexion angle in the sagittal plane of the affected leg was calculated from the markers on the major trochanter, the lateral epicondylus, and the lateral malleolus. The smallest flexion angle during the stance phase was taken as the maximum knee extension. In the present research 180 represents full knee extension, >180 represents hyperextension.

2.5. Dual task

The dual-task consisted of a Stroop test requiring a verbal response on an auditory stimulus, which was taped on a cassette recorder. Patients responded by saying 'yes' when they heard the word 'red' and 'no' when they heard the word 'blue'. Patients were encouraged to respond correctly and as quickly as possible. The interval between two words was 1.5 s and the order of the words was random. The assumption of a dual-task paradigm is that central processing capacity is limited and that in stroke patients the capacity must be divided between two concurrent tasks, a motor task and a cognitive task. The motor task (walking) is the primary task and the cognitive task is the secondary task [19].

2.6. Patient satisfaction

Patients were asked to fill in a questionnaire derived from that described by Tyson et al., [8] who investigated walking with an AFO and translated in Dutch. The questionnaire addressed questions such as the ease of lifting the foot, of swing progression and of weight taking in stance phase. Additional aspects that were asked for were confidence, perceived safety and estimated speed and walking distance. Each item could be answered with 'much improved', 'a little improved', 'no difference', 'a little worse' or 'much worse'.

2.7. Data analyses

Per person the average of two trials for each condition was used for the analysis. Gait characteristics were averaged over at least four steps per trial. Since the data were not normally distributed a non-parametric Wilcoxon signed rank test was used to determine differences between conditions. The global effect of the verbal dual task and the effect of the dual task per condition were determined by comparing walking with and without the dual task independent of the type of shoe and for the orthopaedic shoe and normal shoes separately. The difference in effect of the verbal dual task on walking with the orthopaedic shoe and normal shoes was determined by comparing the percentual difference between walking with and without dual task for the normal shoe and the orthopaedic shoe condition with the Wilcoxon signed rank test. In addition, differences between the conditions with a dual task were determined.

The questionnaire was analysed using descriptive statistics. The item scores ranged from +2 for 'much improved' to -2 for 'much worse'. To determine the overall satisfaction, a sum score was calculated for each patient by adding the scores on the seven items. A one-sample *t*-test was used to determine if the average sum score of all patients differed from zero (no change).

For all analyses SPSS version 15.0 was used and an alpha ≤ 0.05 was considered statistically significant. An improvement of 10% on functional mobility and walking speed was a priori considered as clinically relevant.

Table 1
Characteristics of the patients ($n=19$).

	Mean (SD)	Range
Muscle tone plantar flexor ^a	1 (0.6)	1–3
Motricity index	53 (15)	28–83
Time wearing orthopaedic shoe per day (h)	10 (2.6)	6–15
Walking time per day (h)	3.2 (2.0)	0.5–7

^a Muscle tone was measured with the Modified Ashworth Scale.

3. Results

Nineteen patients (12 males and 7 females) with a mean age of 55 years (SD 10 years, range 32–55 years) were included. Twelve patients had a right and seven a left hemiplegia. Eleven patients had ischemic and eight hemorrhagic strokes. Mean time post stroke was 3.6 months (SD 1.4 months, range 2–8 months). Additional characteristics such as muscle tone and motricity index are shown in Table 1. One patient was unable to perform the verbal dual task due to severe aphasia.

3.1. Effect on functional mobility, walking speed and gait characteristics

Significant and clinically relevant differences were found in TUG (reduction of 22%), walking speed (increase of 37%), step length of the affected (increase of 12%) and non-affected leg (increase of 34%), stance duration of the affected (decrease of 18%) and non-affected leg (decrease of 16%), step width (decrease of 12%) and cadence (increase of 17%) in favour of the orthopaedic shoe (Table 2). No significant differences were found for clearance and knee extension.

Table 2
Outcomes for the 2 shoe conditions, without the dual task ($n=19$).

	Normal shoes Mean (SD)	Orthopaedic shoe Mean (SD)	Difference (%)	p -value [†]
TUG (s)	46.2 (31.5)	36.1 (22.6)	–22	.000 [‡]
Walking speed (m/s)	.27 (.15)	.37 (.21)	37	.000 [‡]
Step length affected leg (m)	.41 (.17)	.46 (.21)	12	.02 [‡]
Step length non-affected leg (m)	.29 (.24)	.39 (.24)	34	.005 [‡]
Stance duration affected leg (s)	1.7 (.7)	1.4 (.6)	–18	.003 [‡]
Stance duration non-affected (s)	1.9 (.8)	1.6 (.6)	–16	.003 [‡]
Clearance (m)	.04 (.03)	.04 (.02)	0	.23
Step width (m)	.25 (.12)	.22 (.08)	–12	.03 [‡]
Knee extension ^a (degrees)	167 (13)	165 (12)	–1	.09
Cadence (steps/min)	47.3 (17.3)	55.3 (23.0)	17	.004 [‡]

^a Maximum knee extension during stance phase, 180 represents full extension, >180 represents hyperextension.

[†] p -values according to Wilcoxon signed rank test.

[‡] $p < 0.05$.

3.2. Effect of the verbal dual task

Independent of the shoe condition, the dual task interfered with functional mobility (TUG) ($Z = -3.87$; $p < 0.001$). Interference of the dual task with functional mobility was found in both shoe conditions; normal shoe condition ($Z = -2.41$; $p \leq 0.02$) and orthopaedic shoe condition ($Z = -3.11$; $p < 0.001$). No interference was found with walking speed and other gait characteristics.

Comparison of the effect of the verbal dual task between the normal shoe condition and the orthopaedic shoe condition is shown in Table 3. There were no significant differences found between the effect of the dual task on all measured parameters in the normal shoe condition and in the orthopaedic shoe condition.

Comparison of walking with the orthopaedic shoe and with normal shoes combined with a dual task is shown in Table 4. Significant differences were found in favour of the orthopaedic shoe in TUG (decrease of 19%), walking speed (increase of 32%), step length of the affected (increase of 13%) and non-affected leg (increase 24%), stance duration of the affected (decrease of 6%) and non affected leg (decrease of 11%), knee extension (decrease 2%) and cadence (increase of 18%).

3.3. Patient satisfaction

Walking distance, safety and confidence improved in over 90% of the patients. Walking speed improved in 84%, swing progression in 74% and lifting of the foot in 69%. 33% of the patients reported that lifting the foot was more difficult while wearing the orthopaedic shoe. The sumscores for overall satisfaction were in favour for the orthopaedic shoe ($t = 9.01$; $p < 0.001$; Table 4).

Table 3
Outcomes for the normal shoe and orthopaedic shoe condition with and without dual task ($n=18$).

	Normal shoes Mean (SD)	Normal shoes + dual task Mean (SD)	Difference normal shoe with and without dual task (%)	Orthopaedic shoe Mean (SD)	Orthopaedic shoe + dual task Mean (SD)	Difference orthopaedic shoe with and without dual task (%)	p -value [†]
TUG (s)	42.0 (26.4)	47.2 (31.4)	12	33.7 (20.6)	38.4 (22.6)	14	.77
Walking (m/s)	.28 (.15)	.28 (.15)	0	.39 (.21)	.37 (.21)	–5	.16
Step length affected leg (m)	.41 (.17)	.40 (.17)	–2	.45 (.21)	.45 (.18)	0	.46
Step length non-affected leg (m)	.28 (.25)	.29 (.23)	4	.39 (.24)	.36 (.26)	–8	.11
Stance duration affected leg (s)	1.6 (.6)	1.5 (.6)	–6	1.3 (.6)	1.4 (.6)	8	.23
Stance duration non-affected (s)	1.8 (.6)	1.8 (.6)	0	1.6 (.6)	1.6 (.6)	0	.17
Clearance (m)	.04 (.02)	.04 (.02)	0	.04 (.02)	.04 (.02)	0	.62
Step width (m)	.26 (.11)	.28 (.19)	8	.22 (.08)	.24 (.09)	9	.46
Knee extension ^a (degrees)	167 (13)	167 (13)	0	164 (12)	164 (12)	0	.80
Cadence (steps/min)	48.9 (16.3)	49.0 (22.3)	0	57.3 (22.0)	57.9 (23.8)	1	.50

^a Maximum knee extension during stance phase, 180 represents full extension, >180 represents hyperextension.

[†] p -values according to Wilcoxon signed rank test (comparison of the effects of the dual task between normal shoe and orthopaedic shoe condition).

Table 4
Outcomes for the 2 shoe conditions, with the dual task ($n=18$).

	Normal shoes Mean (SD)	Orthopaedic shoe Mean (SD)	Difference (%)	p -value [†]
TUG (s)	47.2 (31.4)	38.4 (22.6)	–19	.00 [‡]
Walking speed (m/s)	.28 (.15)	.37 (.21)	32	.00 [‡]
Step length affected leg (m)	.40 (.17)	.45 (.18)	13	.01 [‡]
Step length non-affected leg (m)	.29 (.23)	.36 (.26)	24	.00 [‡]
Stance duration affected leg (s)	1.5 (.6)	1.4 (.6)	–6	.00 [‡]
Stance duration non-affected (s)	1.8 (.6)	1.6 (.6)	–11	.00 [‡]
Clearance (m)	.04 (.02)	.04 (.02)	0	.54
Step width (m)	.28 (.19)	.24 (.09)	–14	.11
Knee extension ^a (degrees)	167 (13)	164 (12)	–2	.01 [‡]
Cadence (steps/min)	49.0 (22.3)	57.9 (23.8)	18	.00 [‡]

^a Maximum knee extension during stance phase, 180 represents full extension, >180 represents hyperextension.

[†] p -values according to Wilcoxon signed rank test.

[‡] $p < 0.05$.

4. Discussion

The present study shows that despite the relatively small number of subjects stroke patients improve considerably in functional mobility (22%) as measured with the TUG test and in walking speed (37%) while wearing a temporary high orthopaedic shoe compared to wearing normal shoes. Also large significant improvements are found in gait characteristics (range: 16%–34%). Decrease in stance duration and step width indicates improved balance during walking wearing a high orthopaedic shoe.

Wit de et al. [9] defined a difference of 10 s in TUG score as clinically relevant. This was based on the study of Podsiadlo et al. [20] who correlated levels of independency with categories of TUG scores. The mean difference in TUG score between the orthopaedic shoe and the normal shoe condition found in the present study was 10 s, and was therefore also clinically relevant according to the criteria of the above mentioned authors. A change in walking speed is considered clinically relevant when it reflects a change in functional walking category (change >35%) [9,21]. The 37% improvement in walking speed in the present study would also be clinically relevant according to these criteria.

Overall, for both the normal and orthopaedic shoe the verbal dual task interfered with functional mobility. Despite the fact that the effect of the verbal dual task was the same for the normal and orthopaedic shoe the high orthopaedic shoe improves functional mobility in dual task conditions. No interference of the dual task was found with walking speed and other gait characteristics. It is well possible that longer periods of training with the high orthopaedic shoe results in a higher level of automaticity of walking. This would make patients even less susceptible to dual task interference and may result in smaller effect of the dual task while walking with orthopaedic shoes.

According to the subjective evaluation, a majority of subjects reported improvement on all evaluated items. 33% reported a deterioration in lifting the foot with respect to the orthopaedic shoe. If foot lifting interferes with safe walking the patient is instructed to walk only under close supervision of the physical therapist or nursing staff. The larger weight of the orthopaedic shoe might be an issue in foot lifting problems. Sometimes these shoes make the difference in walking or not walking. The current article focuses on patients with severe equinovarus and/or knee hyperextension in whom the shoe facilitates ambulation during and outside therapy sessions. When the temporary shoe is replaced by definite custom made shoes and foot lifting remains a problem we overcorrect the contralateral shoe thus inducing a leg length difference with a relative shortness of the paretic leg. Preferably, items about efficiency and general satisfaction should be added to the present questionnaire to determine the overall

usability of the orthopaedic shoe. Jannink et al. [22,23] used such a questionnaire to evaluate these issues after 3 months experience with the shoe.

It should be noted that this study concerns a relatively poor functioning population of stroke patients with a slow walking speed. The average walking speed reflects “unlimited household walkers” and “most limited community walkers” [21]. From a clinical perspective these patients have poor knee control, equinovarus deformity often with a Brunnstrom stage of recovery of 2–3 (ranging from spasticity with basic synergy patterns (stage 2) to some voluntary control of synergies with increasing spasticity (stage 3)).

5. Conclusion

This study showed that a temporary high orthopaedic shoe improves functional mobility, walking speed and gait characteristics in stroke patients. Dual task interference indicates that walking is an attention demanding task, even with high orthopaedic shoes. In spite of an equally big dual task interference with an orthopaedic shoe and normal shoes, high orthopaedic shoe can still improve functional mobility compared to normal shoes. Overall patients were satisfied with the high orthopaedic shoe. In a longitudinal study it would be interesting to monitor whether or not this dual task interference diminishes over time. Future research should furthermore address the question whether a high orthopaedic shoe is still adequate in more complex every day life situations.

Conflict of interest

None.

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