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The effect of an ankle-foot orthosis on walking ability in chronic stroke patients: a randomized controlled trial

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Objective: Regaining walking ability is a major goal during the rehabilitation of stroke patients. To support this process an ankle-foot orthosis (AFO) is often prescribed. The aim of this study is to investigate the effect of an AFO on walking ability in chronic stroke patients.
Design: Cross-over design with randomization for the interventions.
Methods: Twenty chronic stroke patients, wearing an AFO for at least six months, were included. Walking ability was operationalized as comfortable walking speed, scores on the timed up and go (TUG) test and stairs test. Patients were measured with and without their AFO, the sequence of which was randomized. Additionally, subjective impressions of self-confidence and difficulty of the tasks were scored. Clinically relevant differences based on literature were defined for walking speed (20 cm/s), the TUG test (10 s). Gathered data were statistically analysed using a paired *t*-test.
Results: The mean difference in favour of the AFO in walking speed was 4.8 cm/s (95% CI 0.85–8.7), in the TUG test 3.6 s (95% CI 2.4–4.8) and in the stairs test 8.6 s (95% CI 3.1–14.1). Sixty-five per cent of the patients experienced less difficulty and 70% of the patients felt more self-confident while wearing the AFO.
Conclusions: The effect of an AFO on walking ability is statistically significant, but compared with the a priori defined differences it is too small to be clinically relevant. The effect on self-confidence suggests that other factors might play an important role in the motivation to use an AFO.

Introduction

Walking ability after stroke is often disturbed because of muscle weakness, spasticity, impaired sensorimotor control or loss of cognitive functions. Yet regaining the ability to walk is a major goal during the rehabilitation of stroke patients.[1] Often ankle-foot orthoses (AFO) are used to support this goal. An AFO is generally prescribed to provide mediolateral stability at the ankle in stance phase, facilitating toe clearance in swing phase and promoting heel strike.[2] In practice in the Netherlands often different types of plastic, nonarticulated, off the shelf AFOs and articulated metal double-bar braces are used.

Literature reveals only one randomized controlled trial concerning the effect of an AFO on walking in stroke patients.[3] In this study no beneficial effects of an AFO on walking ability

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were found, neither statistically significant nor clinically relevant.

Other studies, however, suggest improvement in walking speed,[4–11] gait pattern[4,10,12] and stride length.[6,8,9]

Although AFOs are thought to have beneficial effects on functional walking ability, results reported in the literature are scarce and inconsistent.[2,3,11] Only one study assessed the effect of an AFO on functional outcome,[11] suggesting an improvement of functional walking ability using the Functional Ambulation Categories.[13] In a systematic review Leung and Moseley[2] reported a dominance of positive studies suggesting improvement of walking speed. The significance of these changes on daily functioning (clinical relevance) and implications for the wider population however remain unresolved.

The literature is not conclusive and especially the effect of an AFO on daily practice remains unknown. The aim of this study, therefore, was to investigate the effect size and clinical relevance of an AFO on walking ability in chronic stroke patients already wearing an AFO.

Methods

Subjects

Patients were recruited from the Rehabilitation Centre 'The Roessingh' in Enschede and from the Department of Rehabilitation of the 'Twenteborg' hospital in Almelo, the Netherlands.

Stroke patients were eligible for the study if they were between 40 and 75 years old and had a first unilateral ischaemic or haemorrhagic stroke from the middle cerebral artery. Patients had to be at least six months post stroke and had to wear a plastic, nonarticulated ankle-foot orthosis daily for at least six months. Patients had to be able to walk independently with shoes with and without orthosis (walking aids were permitted). Furthermore sufficient communication (measured with Utrechts Communication Examination, UCO),[14] cognitive abilities (measured with Mini-mental State Examination, MMSE)[15] and a satisfactory condition were required for full participation in the study.

Patients were excluded if they had more than one stroke, had other diseases negatively influencing walking ability or were unable to walk independently.

Ethical approval was obtained from the medical ethics committee board of 'The Roessingh' Rehabilitation Centre and the 'Twenteborg' hospital. All subjects signed an informed consent before participating.

Ankle-foot orthoses

Selected patients used plastic, nonarticulated ankle-foot orthoses. Due to small individual differences between the patients the AFOs were of three different types: (1) an AFO with a small posterior steel (Distrac or Dynafo; Ortho Medico, Herzele, Belgium); (2) an AFO with a big posterior steel, sometimes individually made (Camp; Basco Healthcare, Zaandam, the Netherlands), and (3) an AFO with two crossed posterior steels and an open heel (Ottobock; Ottobock, Son en Breugel, the Netherlands). The main function of these AFOs is to facilitate foot clearance during swing phase and improve initial contact.

Outcome measures

The Motricity Index of the affected leg[16] and the Functional Ambulation Category (FAC score)[13] were used to characterize the population.

Walking ability was operationalized using:

1) Comfortable walking speed
2) Timed up and go test
3) Stairs test.

Patients were measured walking with and without their AFO while wearing shoes. The sequence of walking with or without the AFO first was randomized.

1) *Comfortable walking speed* was measured in the gait laboratory on a 10 m walkway. Walking speed was automatically measured with two infra-red beams over a distance of 7.5 m. Patients walked the 10-m walkway three times. The average walking speed was calculated and used for further analysis.
2) *Timed up and go test (TUG)*. In this test the patient is timed while he or she rises from a

chair, walks 3 m, turns, walks back and sits down again. Patients were permitted to use a walking aid, but no physical help. The same standard chair with seat height 47 cm and arm height 67 cm was used for all the patients. Patients were allowed to practise the test once before being timed. The TUG is a reliable and valid test for quantifying functional walking ability in elderly people with different kind of medical history, including strokes.[17] In stroke patients the TUG might be expected to be highly responsive as long as the gait speed is not too close to normal values.[18] The TUG was measured three times. The average time needed was calculated and used for further analysis.

3) *Stairs test*, being an extended version of the TUG, including the same tasks from the TUG, with addition of two tasks: stair ascent and descent.[18] Due to practical circumstances the test was slightly modified. Patients were timed while they rose from a chair, walked 1.18 m, ascended a flight of 12 stairs, walked 1.64 m, touched the wall, turned around, descended the stairs, walked back to the chair and sat down. They were allowed to use a walking aid and the rail of the stairs, if necessary. The same chair was used as in the TUG and the stairs used had 12 steps 25 cm deep and 16.5 cm high (the rise percentage is 66%). The stairs were 1 m wide, with a rail on both sides. The instructions before the test and the procedure were the same as in the TUG. Richards[18] found that this test can detect improvements in patients with a moderate to normal walking speed. The stairs test was measured three times. The average time needed was calculated and used for further analysis.

Additionally, after the TUG and the stairs test, with and without the AFO, patients were asked to express their subjective impressions considering self-confidence and difficulty of the tests using two five-point rating scales:

- Self-confidence: 1 = very insecure, 2 = insecure, 3 = neither insecure, nor secure, 4 = secure and 5 = very secure.
- Difficulty: 1 = very difficult, 2 = difficult, 3 = neither difficult, nor easy, 4 = easy and 5 = very easy.

Data analyses

Walking speed, TUG and stairs test were statistically analysed using a paired *t*-test in SPSS. Subjective impressions of the patients concerning self-confidence and difficulty were analysed by means of the Wilcoxon signed ranks test in SPSS.

The main interest of this study concerned the significance of the observed changes for daily functioning (clinical relevance). Hence clinically relevant effect sizes were defined prior to the study.

1) *Walking speed:* Based on the study of Perry *et al.*[19] a difference of 20 cm/s in walking speed with and without the AFO was defined as clinically relevant. Perry assigned the walking speed to six categories of functional walking ability, the modified Hoffer Functional Ambulation Scale. Taking the inclusion criteria into account (able to walk independently), the last three categories of this scale (most-limited, least-limited community and community walkers) were judged as the most important. Between these categories a mean difference in walking speed of approximately 20 cm/s was observed.
2) *Timed up and go test:* For this test a difference of 10 seconds was defined as clinically relevant. This was based on the study of Podsiadlo and Richardson.[17] Podsiadlo described significant differences in Barthel scores (and independency) with a TUG score of less than 20, 20–30 and more than 30 seconds.
3) *Stairs test:* No suggestion for clinically relevant differences could be extracted from the literature. Based on the defined clinical relevant differences of the TUG and taking into account the stairs test takes more time to perform, a clinical relevant difference of 15 seconds was defined by the authors.
4) *Subjective impressions of the patients concerning self-confidence and difficulty*: Authors defined any improvement

of one point on these scales as clinically relevant.

Results

Study population

Between February 2002 and November 2002, 20 stroke patients were included in the study. Figure 1 shows a flowchart describing the flow of the patients throughout the study.

Twelve men and eight women participated in the study with a mean age of 61.2 years old (range 41–73 years) and a mean time since stroke of 25.6 months (range 8–48 months). Mean time since start of using an AFO was 20.9 months (range 6–44 months). Eighteen patients had an ischaemic stroke and two a haemorrhagic stroke; 11 patients had a left hemiplegia and nine a right hemiplegia. The median Motricity Index for the affected leg was 58.0 (interquartile range (IQR) 27.0) and the median FAC score was 4.5 (IQR 1.0). All patients had sufficient communicative (median UCO 6.0 and IQR 0.8) and cognitive abilities (median MMSE 26.0 and IQR 2.8) to participate in the study.

Table 1 shows the baseline characteristics for the two randomized groups; group 1 walked with the AFO first and group 2 without the AFO first. The two groups were comparable for baseline characteristics. Consequently the results of the two groups were pooled.

Effect on walking ability

Table 2 shows the descriptive statistics and the results of the paired t-test (p-values) for all tests.

The mean difference in favour of the AFO for walking speed was 4.8 cm/s (95% CI 0.85 −8.7), for the TUG test 3.6 s (95% CI 2.4–4.8) and for the stairs test 8.6 s (95% CI 3.1–14.1). Results show a statistically significant effect in favour of the AFO in walking speed, TUG and stair test.

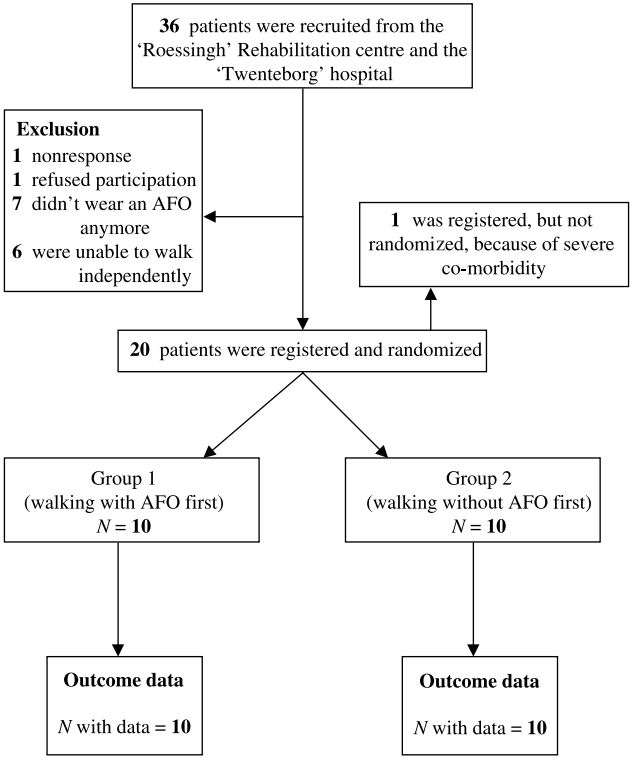

Figure 1 Flowchart of patients through the study.

Table 1 Baseline characteristics in the two randomization groups

	Group 1 (AFO–without AFO)	Group 2 (Without AFO–AFO)
Age years (range)	61.1 (51–73)	61.2 (41–70)
Time since stroke, months (range)	26.9 (8–42)	24.2 (8–48)
Time wearing AFO, months (range)	20.8 (6–39)	20.9 (6–44)
Ischaemic/haemorrhagic strokes	9/1	9/1
Left/right hemisphere	7/3	4/6
Median UCO (IQR)	6 (0.3)	6 (1.3)
Median MMSE (IQR)	25.5 (3.8)	26.5 (3.5)
Median Motricity Index, affected leg (IQR)	59.5 (26)	53.0 (28.3)
Median FAC score (IQR)	4.5 (1)	4.5 (1)

IQR, interquartile range; UCO, Utrechts Communication Examination.

However, when taken into account the a priori defined values none of these effects can be described as clinically relevant (Figure 2).

Effect on subjective impressions

Of all patients 65% (13/20) experienced less difficulties (p-value $=0.001$) and 70% (14/20) felt more self-confident (p-value $=0.005$) while wearing the AFO (≥ 1 point change on the scales). In both difficulty and self-confidence 25% (5/20) of the patients scored no effect of the AFO. In contrast to the tests for walking ability these differences were judged as clinically relevant.

Discussion

The aim of this study was to investigate the clinically relevant effect of an AFO on walking ability in chronic stroke patients already wearing an AFO.

Results show that the effect of an AFO on walking ability and subjective impressions are statistically significant. Compared to the a priori defined values however, these differences are too small to be considered clinically relevant, which is in agreement with earlier findings of Beckerman *et al*.[3]

The subjective impressions obtained with the questions about difficulty and self-confidence are clearly in favour of the AFO and judged as clinically relevant. We acknowledge the procedure to ask for self-confidence and difficulty with a five-point scale has no well established validity and reliability, but was considered an important outcome that had to be highlighted in this study. Most patients felt more self-confident and experienced less difficulty during the measurements when wearing an AFO. This is comparable to the findings in the study of Tyson.[11]

In the present study 14 out of 20 patients mentioned the beneficial effects of the AFO. Five patients mentioned no effect performing the tasks

Table 2 Descriptive statistics and results of paired t-test (p-values)

	Velocity (cm/s) with AFO	Velocity (cm/s) without AFO	Velocity (cm/s) difference	Timed up and go (s) with AFO	Timed up and go (s) without AFO	Timed up and go (s) difference	Stairs (s) with AFO	Stairs (s) without AFO	Stairs (s) difference
Mean (SD)	49.6 (24.3)	44.9 (24.0)	4.8 (8.4)	25.6 (11.7)	29.2 (12.9)	3.6 (2.5)	73.0 (37.8)	81.6 (44.4)	8.6 (11.8)
Median	44.2	34.3	4.2	23.3	29.3	3.2	68.6	74.5	3.4
Minimum	18.0	18.0	−17.0	10.3	10.5	0.2	27.4	27.8	−3.3
Maximum	93.0	93.0	24.0	49.7	56.7	8.1	157.9	181.8	34.1
Interquartile range	37.7	43.9	0.1	19.6	23.8	4.9	59.2	68.1	15.9
p-value t-test			0.020			0.000			0.004

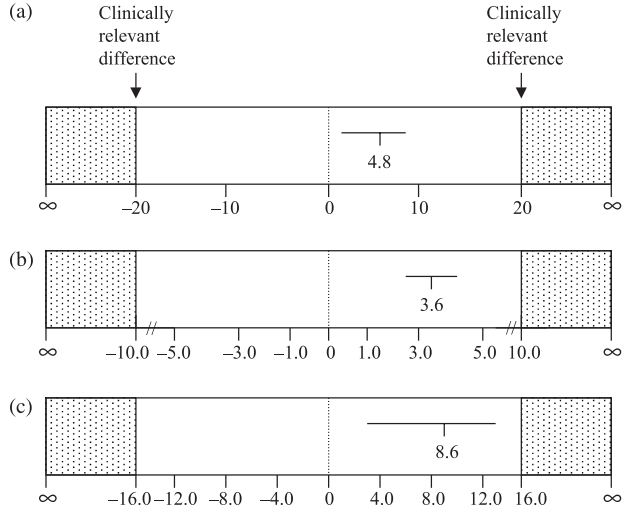

Figure 2 Effect AFO on walking ability. (a) Walking speed (cm/s), mean difference and 95% CI. (b) Timed up and go test (s), mean difference and 95% CI. (c) Stairs test (s), mean difference and 95% CI.

with or without the AFO. One patient mentioned even a worse performance of the tasks with the AFO. In trying to find an explanation for this difference, baseline characteristics of the patients were evaluated. All but one patient experiencing no effect of the AFO had a Motricity Index score for the affected leg $\geq$60 points. Most of the patients mentioning beneficial effects of the AFO had a Motricity Index for the leg $\leq$60 points. The only patient mentioning worse effects of the AFO also had a Motricity Index score for the leg $\geq$60 points. It appears that patients with a better function of their leg experience less beneficial effects of an AFO compared with the more affected patients.

Although the number of patients included in the study was relatively small, the effects were statistically significant. Including more patients theoretically will only change the width of the confidence interval, but would not change the overall conclusion. The relatively small number of patients included is inherent to the aim of the study (clinical relevance of the nonarticulated AFO for daily practice). Homogeneity of the study population was considered to be very important. The population therefore was highly selected, which of course may limit the generalization of the results.

The mean difference in walking speed in favour of the AFO is 4.8 cm/s (95% CI 0.85–8.7). This finding is comparable with findings from literature; Leung and Moseley[2] reported on four studies comparing walking with AFO versus walking with shoes (as in this study). The mean differences in walking speed in these four studies varied between 0 and 12.0 cm/s with a moderate degree of variability in 95% confidence interval.

The clinically relevant differences for walking speed and TUG test were based on the studies of Perry *et al*.[19] and Podsiadlo and Richardson[17] respectively. When using the computed differences in walking speed for each individual patient, walking with and without an AFO, only four subjects changed to a higher category in Perry's classification. Based on the outcomes of the TUG only five subjects changed to a higher score on the Barthel Index. These results are

Clinical messages

- Although the effect of an ankle-foot orthosis (AFO) on walking ability is statistically significant, detected differences are too small to consider clinically revelant.
- The positive effect on self-confidence suggests that 'safety' plays an important role in the motivation to use an AFO.

in contrast with the findings of Tyson and Thornton.[11] They concluded that most of the patients improved in functional walking ability using the FAC (median FAC without AFO is 2 and with AFO is 4). Differences in outcome may be due to differences in population; Tyson included acute stroke patients whereas in this study only chronic stroke patients, at least six months post stroke and walking with an AFO for at least six months, were included.

The a priori defined, clinically relevant differences chosen for the TUG were perhaps arbitrary and too high. In the studies of Geiger *et al*.[20] and Ahmed *et al*.[21] smaller differences in TUG score were found, respectively after physical therapy (mean difference 8.46 seconds) and during recovery after stroke (mean difference 9 seconds after five weeks and 0 seconds from five weeks to three months). On the other hand the a priori chosen differences were related to functional scores, the modified Hoffer Functional Ambulation Scale and the Barthel Index. Perhaps one has to accept that the effect of an AFO is too small to be clinically relevant. Lehmann[22] already stated that 'one must recognize that these orthoses are worn by many patients who can walk without them but who cannot walk safely'. If this is true, safety should be the prime motivation for prescribing an AFO rather then walking ability.

In conclusion, for patients using an AFO for everyday activities post stroke, the AFO is beneficial for their walking ability. Differences in walking speed, TUG test and stairs test are statistically significant in favour of the AFO. Hence most patients feel more self-confident and experience less difficulty performing the measurements while wearing an AFO. Clinical relevance for daily functioning, however, remains unclear.

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