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Immediate effects of an individually designed functional ankle-foot orthosis on stance and gait in hemiparetic patients

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Objective: To evaluate the immediate effects of individually designed functional in-shoe ankle-foot orthoses (AFO) made of soft and hard cast on balance, standing, and gait parameters in hemiparetic patients.
Design: Crossover design with randomized order of the intervention.
Setting: A rehabilitation centre for adults with neurological disorders.
Subjects: Twenty-eight patients with hemiparesis due to stroke or traumatic brain injury.
Measures: Postural sway, standing and gait parameters based on ground reaction forces in two conditions: Patients were randomly assigned to varying sequences of wearing AFO in footwear or wearing footwear alone.
Results: AFO significantly improved weight-bearing on the affected leg (affected/unaffected side symmetry: 2.25 ± 1.5 with AFO versus 3.4 ± 2.5 without AFO, $P < 0.05$) and postural sway in stance (12.5 mm $\pm$ 5.2 with AFO versus 15.7 mm $\pm$ 6.7 without AFO, $P < 0.05$), double stance duration (21.1 ± 14.4% of gait cycle with AFO versus 25.9 ± 21.6% of gait cycle without AFO, $P < 0.05$), and symmetry ratios of gait parameters such as stance duration (2.0 ± 1.5 s with AFO versus 3.3 ± 3.6 s without AFO, $P < 0.05$) and deceleration forces (1.6 ± 0.5 with AFO versus 1.9 ± 0.6 without AFO, $P < 0.05$) during gait. No significant differences were observed in all other symmetry ratios of gait parameters.
Conclusion: An individually designed functional in-shoe AFO can improve stance and gait parameters, even in a single use, in patients with hemiparesis.

Introduction

In patients with brain injury, the automatic postural response is often disrupted by hemiparesis. Hemiparesis frequently contributes to impairments in standing balance, leading to difficulty in walking and increased risk of falling.[1] Physiotherapy aims, therefore, to improve balance and to reduce postural sway in these patients.[2] As an adjunct to therapy, ankle-foot orthoses (AFO) are frequently used to improve gait pattern[3–6] and/or gait speed[7] of hemiparetic patients. AFO can improve spatio-temporal parameters of gait[8] and lower the energy costs of walking.[7] However, to this point, little is known about possible effects of an AFO on either symmetrical weight-bearing in stance or symmetry of gait in patients with hemiparesis.[9]

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Different types of AFO for patients with hemiparesis have been described in the past.[10–15] Hesse *et al*. described the optimal AFO as an individually designed, lightweight, in-shoe orthosis which would allow a dorsal extension/plantarflexion stop for the ankle joint with a roll-off over the front of the foot.[16]

According to these guidelines we developed an individually designed and easily produced AFO.[17] This new in-shoe AFO is made of soft- and hardcast, and fulfilled all the recommendations for patients with hemiparesis brought up by Hesse *et al*.[16] The calliper can easily be made in 15 min. The AFO is lightweight, is cosmetically acceptable and may prevent varus deformity. In comparison with other AFOs, the plantar- and dorsiflexor stop cannot be set and the lever arm is rather short, which indicates an optimal use in patients with less severe hemiparesis. Our AFO is very cheap to produce, and was developed as a temporary walking aid for use until the fitting of a final AFO. However, because no data have been published on this new kind of orthosis the authors wished to evaluate the benefits of this new AFO on weight-bearing in stance and on gait symmetry parameters.

The aim of the present study was to evaluate the influence of this new, individually designed AFO on some stance and gait parameters in hemiparetic patients.

Methods

Inclusion criteria for the study were patients with hemiparesis due to traumatic brain injury or stroke, who had used an AFO for less than one week, were able both to stand without assistant device for 20 s and to walk 15 m both with and without walking aids (Functional Ambulation Category[18] 2–5).

Exclusion criteria were obvious ankle contracture (plantigrade posture after 15 min of standing in an upright position), a marked increase in muscle tone through most of the range of motion in ankle, knee, or hip joint (Modified Ashworth Scale[19] score more than 2), and/or patients who could not collaborate due to different neurological symptoms (e.g. pusher or neglect syndrome, aphasia). The study was conducted with the understanding and written consent of each patient.

The production of the individually designed AFO has been described in detail in a recent publication of the authors.[17] Therefore, this procedure will be only briefly described. A combination of soft- and hardcast material (3M Health Care, Neuss, Germany) was used. The ankle was covered with a stockinet, and a semi-circular padding for prominent skin was applied. A half roll of softcast (7.6 cm × 3.6 m) was applied using a special circular winding technique.[20] A longuette of hardcast material (7.5 cm × 20 cm 3M Health Care, Neuss, Germany) was placed on top and covered with the remaining half roll of softcast. The construction of one AFO takes approximately 15 min. One hour after manufacturing and drying, the AFO is ready for use (Figure 1). The material cost is approximately 25 euro for one AFO.

The AFO is semi-rigid, encasing the ankle to a height of approximately 20 cm (±5 cm), and is therefore biomechanically similar to commonly used thermoplastic models (e.g. 'Dyna Ankle', Otto Bock HealthCare GmbH, Duderstadt, Germany). The AFO is quasi double-stopped (can be set within the range of 80° (−10° dorsal extension) to 90° (which means neutral zero position)). The AFO does not encase the metatarsophalangeal joints, and allows therefore a roll-off over the

Figure 1 One hour after manufacturing and drying, the orthosis is ready for use. The orthosis does not encase the metatarsophalangeal joints, and therefore allows a roll-off over the front of the foot. A fastener (black coloured) is placed over the AFO. As shown, the orthosis can be worn in patient footwear.

front of the foot (Figure 1). Each AFO used was individually adjusted to the kinesiological disorder of the patient (e.g. the arch individually adjusted and corrected for prevention of valgus deformity).

All patients practised walking with and without orthosis before the gait analysis was performed. The AFO was checked during this time for proper fitting, and any necessary adjustments were made. Additionally, a 5-min warm-up with and without AFO was provided to familiarize the patient with the gait laboratory.

Measurements

Each patient was examined wearing his or her standard footwear.[4] Subjects were recorded while wearing their AFO in the footwear, and also while wearing their footwear alone. The order of testing was randomly assigned. Randomization was provided with sealed and numbered envelopes. For every patient, postural sway measurement and gait analysis were performed. Because of its potential influence on postural sway, the use of a stick or similar support was not allowed.[21]

Postural sway measurements and weight-bearing symmetry during standing were obtained using the ADDON System (ADDON, Bratislava, Slovakia) as a force platform. All patients were asked to step on to the platform, their feet positioned by the patient in a comfortable position. The patient was then instructed to stand as still as possible in an upright position with arms at their sides looking straight ahead. For better reproducibility of the test position, we marked the position of both feet during first measurement on the sway platform. Postural sway data was recorded for a period of 20 s both in eyes-open and eyes-closed conditions.[22] A total of three trials for each condition were performed (alternating between eyes-open and eyes-closed if possible) and averages were calculated. The platform consisted of a forceplate (ADDON, Bratislava, Slovakia, 45×45 cm) with transducers mounted in all directions along the transversal plane. The output was digitized, and the software provided information about postural sway during standing. A 95% circle of all values of the postural sway area was calculated

Weight-bearing symmetry was measured immediately after postural sway test. Patients were asked to stand as symmetrically as possible for an additional 30 s on the above-mentioned forceplates. Symmetry ratios were calculated according to the formula: weight al/weight ul (al = affected leg, ul = unaffected leg). After measuring stance parameters, gait analysis was performed.

The gait analyses of vertical ground reaction forces were used to objectify gait cycles.[23–25] The system (Fitronik, Bratislava, Slovakia) consists of a segmented platform walkway (8×1.2 m) with two embedded forceplates (60×40 cm).

Once the patient's stride length and pattern had been established after several trials, the orientation of the removable forceplates (either transverse or longitudinal) was adjusted so that double step measurements could be made (sampling rate 2000 Hz).

Patients walked at their self-adapted walking speed. Five double step measurements were recorded. Measurements were repeated when the patient did not hit the embedded forceplates. The measurement data and subsequent analyses were handled using software developed at the Klinik Bavaria.[24] As measurement of gait symmetry the ratio between affected and unaffected leg for the following parameters was calculated (Figure 2): (1) the peak vertical ground reaction force at heel strike (Fz1) and toe off (Fz2) during gait cycle, normalized by body weight (Fz1% and Fz2% respectively) for both legs, (2) the stance time for both legs, (3) the horizontal ground reaction forces during gait cycle for both legs, and (4) the double stance duration as a measurement/indicator of gait velocity and stability. Symmetry ratios were calculated according to the formula: xal/xul (al = affected leg, ul = unaffected leg).[24]

Pairwise comparisons of standing and gait parameters were prepared using the t-test for dependent variables.[26 27] For all statistical tests, significance was set at $P < 0.05$.

Results

A total of 28 subjects (8 female, 20 male), admitted to the Department of Neurological Rehabilitation for inpatient rehabilitation between May 2001 and December 2002, were eligible and fulfilled the inclusion and exclusion criteria. The mean age was 51.7 years (standard deviation 16.1, range 23–77 years), 10 patients suffered from right and 18

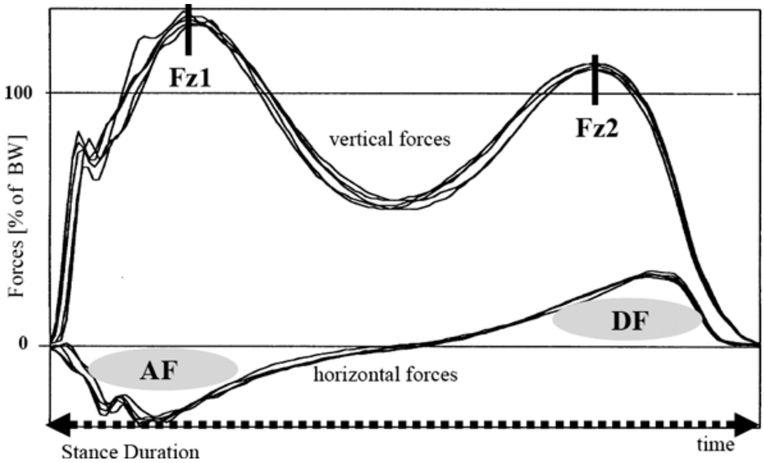

Figure 2 Vertical and horizontal ground reaction forces for one stance duration of one leg. Fz1, peak vertical ground reaction force at heel strike normalized by body weight; Fz2, peak vertical ground reaction force at toe off normalized by body weight; AF, acceleration forces; DF, deceleration forces; stance duration, normalized by 90% of body weight.

from left hemiparesis. The reasons for hemiparesis were stroke in 20 cases and traumatic brain injury in eight cases. The duration of illness was 2.6 months (range 1–6 months).

A significant reduction of postural sway (with eyes open) and an improvement of symmetry in stance were observed while wearing the AFO, as shown in Table 1. Postural sway (with eyes closed) did not improve significantly (Table 1).

During gait a significant reduction of double stance duration with AFO was observed ($21.1 \pm 14.4\%$ versus $25.9 \pm 21.6\%$, $P < 0.05$, as shown in Table 1) and significant differences were revealed with respect to gait symmetry parameters with and

Table 1 Immediate effects of the individually designed AFO on postural sway, stance and gait symmetry parameters

	With AFO[a]	Without AFO[a]	*P*-value[b]
Stance parameters			
Postural sway (mm)			
Eyes open	12.5 ± 5.2	15.7 ± 6.7	0.0026
Eyes closed	22.2 ± 11.2	24.0 ± 11.2	0.107
Stance symmetry [affected/unaffected side][c]	2.25 ± 1.5	3.4 ± 2.5	0.0026
Gait parameters			
Gait symmetry parameters vertical ground reaction forces (affected/unaffected side)[c]			
Fz1 (% of body weight((heel strike)	1.1 ± 0.1	1.1 ± 0.2	n.s.
Fz2 (% of body weight) (toe off)	1.7 ± 0.3	1.6 ± 0.4	n.s.
Stance duration (s) at 90% of body weight	2.0 ± 1.5	3.3 ± 3.6	0.0172
Gait symmetry parameters horizontal ground reaction forces (affected/unaffected side)[c]			
Acceleration forces	1.5 ± 0.7	1.5 ± 0.7	n.s.
Deceleration forces	1.6 ± 0.5	1.9 ± 0.6	0.0014
Double stance duration			
Double stance duration (% of one gait cycle)	21.1 ± 14.4	25.9 ± 21.6	0.0072

[a]Means ± standard deviations.
[b]Determined by two-sided *t*-test for dependent samples ($P > 0.05$ was determined as not significant = n.s.).
[c]A value of 1 means perfect symmetry.
Fz1, peak vertical ground reaction force at heel strike normalized by body weight; Fz2, peak vertical ground reaction force at toe off normalized by body weight.

without AFO (deceleration forces affected/unaffected side and stance time affected/unaffected side, all $P < 0.05$, as shown in Table 1). No significant differences were revealed with respect to other gait symmetry parameters concerning the use or absence of AFO (Fz1 and Fz2 affected/unaffected leg, and acceleration forces affected/unaffected leg, all $P > 0.05$, as shown in Table 1).

Discussion

The present study shows that the immediate effects of an individually designed AFO in hemiparetic patients are a reduction of postural sway with eyes open and an increased weight-bearing on the affected leg in stance, as well as an improvement of some gait parameters.

Balance dysfunction of those patients with hemiparesis who are able to resume standing is typically characterized by increased sway during quiet standing and by an asymmetrical weight distribution between lower limbs. The reduced postural sway in standing while wearing an AFO could be one explanation for increased weight-bearing on the affected leg. In this line Burtner and Woollacott suggested that the use of an AFO significantly improved balance responses in children with cerebral palsy.[28] In our study, however, postural sway was not significantly improved by the use of an AFO when eyes were closed. An explanation for this could be the predictable increase in sway when eyes are closed causing a higher standard deviation of the revealed values (see Table 1), increasing the sample size necessary for ascertaining significant differences of means.

Hesse *et al*. showed improved gait symmetry through the use of an AFO in patients with equinovarus deformity.[5] On the other hand, in hemiparetic patients with marked spasticity Hesse and his colleagues failed to show improvements in gait symmetry through use of an AFO.[29] In the present study we found an improvement in some, though not all, gait symmetry parameters such as stance time and deceleration forces, indicating a more balanced gait when wearing an AFO in patients with hemiparesis (without marked spasticity). Tyson found improvement in gait impairments using a hinged AFO in people with severe hemiparesis and disability. Gait symmetry parameters, however, were unaffected by use of this AFO.[3] Because many clinicians focus on symmetry (e.g. some physiotherapists believe that gait asymmetry is a critical and disabling component[30–32]) one could argue that measuring and treating symmetry is the most important factor. On the other hand improvement in symmetry is not necessarily the same as more 'normal' gait, and is not necessarily indicative of overall improvement. Perhaps improvement of gait in patients with hemiparesis need also be defined in other terms, such as percentage weight taken on the affected leg, or walking speed in general.

Lehmann *et al*. concluded that a less than optimally adjusted AFO could make walking more difficult because of producing knee instability through more exaggerated knee flexion.[33] For this reason we used an individually designed AFO. Manufacturing the AFO used in the study is quick and easy, and production costs are quite low (one therapist and one assistant took approximately 15 min in the construction; the material and salary costs were approximately 20–25 euro). However, in our clinical experience, this advantage is somewhat mitigated by a low durability (approximately eight weeks) of the described AFO. However, the AFO can be useful as a model for a longer lasting calliper (e.g. thermopropylene or metallic with longer lever arm). Additionally, after recovery and successful rehabilitation of hemiparesis, an AFO is often no longer necessary. Thus, in the view of the authors, the AFO described in this study may serve two roles: as a model for the development of a more expensive and durable AFO based on the one presented here, and as a

Clinical messages

In mildly impaired hemiparetic patients, immediate effects of an individually designed AFO are:

- a reduction of postural sway and more weight-bearing on the affected leg in stance and
- an improvement in some, but not all, parameters of gait analysis.

temporary measure for use in hemiparetic patients with good prognosis and response to therapy.

The study, however, has some limitations. Basic gait cycle parameters such as gait speed and stride length were not investigated in this study to support the findings of the gait analysis. However, a recently published systematic literature review of Leung and Moseley showed evidence that the use of an AFO can be effective in improving basal gait parameters.[34] Additionally, it is known that double stance duration is inversely correlated with gait speed.[35] In this line and in accordance with findings of other researchers, double stance duration was reduced through use of an AFO.[6,29–33] An additional limitation is that the present study investigated only the immediate effects of the use of an AFO. Whether these effects would persist with sustained use of the described AFO remains undetermined. At least for more spastic patients the investigated AFO may not be appropriate due to the short lever arm. However, our results might be helpful in the ongoing discussion over the use of AFOs in patients with hemiparesis.

Further research is needed to gain insight into which AFO might be most appropriate for patients with hemiparesis with and without spasticity, and to reveal the effect of combinations of different types of AFOs with various techniques such as muscle stretching and/or botulinum toxin injections.[36] Additionally, further investigations should examine whether the use of an AFO as part of a rehabilitation programme could translate into a quicker or better recovery of functional gait ability.[37]

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