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# A randomized controlled trial on providing ankle-foot orthoses in patients with (sub-)acute stroke: Short-term kinematic and spatiotemporal effects and effects of timing

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ABSTRACT

Initial walking function is often limited after stroke, and regaining walking ability is an important goal in rehabilitation. Various compensatory movement strategies to ensure sufficient foot-clearance are reported. Ankle-foot orthoses (AFOs) are often prescribed to improve foot-clearance and may influence these strategies. However, research studying effects of actual AFO-provision early after stroke is limited. We conducted an explorative randomized controlled trial and aimed to study the short-term effects of AFO-provision on kinematic and spatiotemporal parameters in patients early after stroke. In addition, we studied whether timing of AFO-provision influenced these effects. Unilateral hemiparetic patients maximal six weeks post-stroke were randomly assigned to AFO-provision: early (at inclusion) or delayed (eight weeks later). Three-dimensional gait-analysis with and without AFO in randomized order was performed within two weeks after AFO-provision. Twenty subjects (8 early, 12 delayed) were analyzed. We found significant positive effects of AFO-provision for ankle dorsiflexion at initial contact, foot-off and during swing (−3.6° (7.3) vs 3.0° (3.9); 0.0° (7.4) vs 5.2° (3.7); and −6.1° (7.8) vs 2.6° (3.5), respectively), all $p < 0.001$. No changes in knee, hip and pelvis angles were found after AFO-provision, except for knee (+2.3°) and hip flexion (+1.6°) at initial contact, $p \leq 0.001$. Significant effects of AFO-provision were found for cadence (+2.1 steps/min, $p = 0.026$), stride duration (−0.08 s, $p = 0.015$) and single support duration (+1.0%, $p = 0.002$). Early or delayed AFO-provision after stroke did not affect results. In conclusion, positive short-term effects of AFO-provision were found on ankle kinematics early after stroke. Timing of AFO-provision did not influence the results.

Trial registration number: NTR1930



## 1. Introduction

Initial walking function is limited in two-thirds of patients with acute stroke [1] and regaining this walking ability is an important goal in rehabilitation [2]. Important kinematic changes observed after stroke are decreased ankle dorsiflexion [3–6] and decreased knee [3,5,7] and hip flexion [8] in swing, contributing to insufficient foot-clearance. Various compensatory movement strategies to ensure sufficient foot-clearance after stroke are reported [8], including pelvic hiking [7,9] or pelvic obliquity [10], both in the frontal plane, and circumduction [7,9]. Furthermore, increased hip flexion [6] and a hip abductor pattern [11] are reported. However, kinematic strategies to achieve sufficient foot-clearance are reported to differ between subjects [6,9,11] and are thought to be linked with self-selected walking speed [9].

Ankle-foot orthoses (AFOs) are often prescribed to improve walking. Literature states that AFOs may provide mediolateral stability in stance, facilitate toe-clearance in swing and promote

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heel strike [12]. In a review on the effects of AFO-use after stroke, Tyson et al. reported improvements on ankle kinematics in early stance, swing phase and toe-off and knee kinematics in stance [13]. No effects on knee kinematics in swing or hip kinematics were found. Most studies in this review included chronic stroke patients, of which many were already using AFOs in everyday life and walked independently. One may argue that in these subjects the effect of removing an AFO is tested. Studying effects of the actual AFO-provision early after stroke to patients that are not used to walk with an AFO is more in line with daily clinical practice and therefore could provide more relevant information to clinicians. Measuring the biomechanical effects of AFO-provision early after stroke is relevant, as one may speculate that the development of compensatory movement patterns in proximal lower limb segments may decrease when foot-drop in the distal segment is limited in an early stage because of early AFO-provision. However, studies measuring kinematic and spatiotemporal effects of AFO-provision in subjects with recent stroke are limited [14–16]. In total 37 subjects were included in these three studies, with a mean time since stroke between 24.5 [16] and 67 [14] days. Positive effects on sagittal ankle kinematics were reported [14,15], as well as effects on walking speed [14,15], cadence [14–16], step length [14,16] and stride length [15]. No effects on sagittal knee and hip kinematics were found. Effects of early AFO-provision on frontal plane kinematics and effects on the pelvis were not studied. However, these are considered to be relevant because compensatory strategies in the frontal plane and around the pelvis are reported to be important to achieve toe clearance in the absence of sufficient dorsiflexion provided by the AFO [6,9,10].

The aforementioned considerations show that there is a lack of studies examining kinematic and spatiotemporal effects of the actual provision of AFOs and the timing of this provision early after stroke. Therefore, we conducted an explorative randomized controlled trial to study the effects of providing AFOs on two different moments in the rehabilitation early post-stroke. Effects of AFO-provision on functional outcome measures like balance, walking ability and activities of daily-life were reported previously [17]. The primary aim of the current paper was to study the short-term effects of the AFO-provision on kinematic and spatiotemporal parameters in patients in the early rehabilitation phase post-stroke. The secondary aim was to study whether timing of AFO-provision post-stroke (early or delayed) influenced these effects. We hypothesize that early provision is more beneficial.

## 2. Methods

We designed a single center, randomized, controlled, parallel group study. The study was approved by the Medical Ethical Committee Twente, registered in “the Netherlands Trial Register”, number NTR1930 and followed the CONSORT guidelines [18]. All subjects provided written informed consent. This paper contains a brief description of the study methods; a full description can be found in a previous publication [17].

### 2.1. Subjects

We recruited subjects from the Roessingh, Center for Rehabilitation in Enschede, the Netherlands. Inclusion criteria were: 1) unilateral ischemic or hemorrhagic stroke leading to hemiparesis (single and first-ever stroke or history of previous stroke with full physical recovery); 2) at least 18 years of age; 3) maximal six weeks post-stroke; 4) receiving in-patient rehabilitation care at inclusion; 5) able to follow simple verbal instructions; and 6) indication for AFO-use (i.e. abnormal initial floor contact and/or problems with toe-clearance in swing and/or impaired ability to take bodyweight through the paretic lower limb in stance) determined by the treating rehabilitation physician and physiotherapist. Subjects suffering from severe comprehensive aphasia or neglect or with cardiac, pulmonary or orthopedic disorders that could interfere with gait were excluded.

### 2.2. Randomization

Participants were allocated to one of two intervention-groups using stratified block-randomization: 1) AFO-provision at inclusion, in study week 1 (early group); or 2) AFO-provision eight weeks later, in study week 9 (delayed group). Stratification was based on the Functional Ambulation Categories (FAC) [19]. Walking with (FAC 0–2) and without (FAC 3–5) physical support of another person at inclusion were used as stratification categories.

### 2.3. AFO-provision

Subjects were provided with one of three commonly used types of off-the-shelf, non-articulated, posterior leaf design, polyethylene or polypropylene AFOs: flexible, semi-rigid or rigid (Basko Healthcare, Zaandam, the Netherlands (Fig. 1). All AFOs were worn inside the shoe and included a proximal calf strap. AFO-fitting was performed by a licensed orthotist. AFO-type was chosen according to a custom developed protocol [17], based on the prerequisites of gait [20], determining whether the main walking problems arise in stance, foot-clearance in swing and/or prepositioning at heel strike. The effect of the prescribed AFO was verified and confirmed by the responsible physician in all subjects.

### 2.4. Procedures

Measurements included 3D gait-analysis in one single session, with and without AFO in random order. Measurements were performed after AFO-provision in week 1 or 9 of the study, for the early and delayed group, respectively. The measurements required that subjects were able to walk without physical support of another person (FAC $\geq$ 3) and had sufficient endurance to complete a measurement. If this was not the case, the measurement was postponed until subjects complied with these conditions. We defined that short-term effects of the actual AFO-provision could only be assessed in case measurements could be performed within two weeks after AFO-provision. Therefore, subjects were only included in the analysis in case measurements were performed in week 1–3 (early group) or week 9–11 (delayed group). Besides the AFO-intervention all subjects received usual care from experienced physiotherapists according to the Dutch guidelines for physiotherapy after stroke [21,22].

**Fig. 1.** Three types of AFOs used in the study.
This figure shows the types of AFOs used in the study. From left to right: 1) polyethylene, non-articulated AFO with two crossed posterior steels and open heel, most flexible type; 2) semi-rigid, polypropylene, non-articulated AFO with two crossed posterior steels and open heel, larger posterior steel compared to type 1; 3) rigid, polypropylene, non-articulated AFO with closed posterior steel and closed heel.

### 2.5. Data collection and processing

At inclusion, basic demographic data were recorded. Kinematic and spatiotemporal data were collected in a gait laboratory at 100 Hz using a six-camera Vicon MX13 + motion-analysis system (Vicon, Oxford, UK) for capturing marker trajectories. Reflective 25-mm markers were placed directly on the skin and shoes according to the modified Helen Hayes marker set. Additional to this marker set, two markers were placed on each shoe at metatarsal I and V to assess in/eversion movements. Subjects walked on a level walkway at self-selected walking speed wearing their own shoes. Measurements with and without AFO were performed in random order, without removing the reflective markers. Assistive devices (such as a cane or quad stick) were permitted and it was allowed to rest between the trials to prevent effects of fatigue.

Data processing was performed using the lower-body Plug-In-Gait model from Vicon and custom in-house software, developed in Matlab (MathWorks, Natick, Massachusetts). Initial contact and foot-off were determined manually. Marker trajectories were time-normalised to stride duration and averaged, with 0% representing initial contact and 100% representing the next initial contact of the same foot. Eight to ten representative strides were used for further analysis.

### 2.6. Outcome measures

The primary outcome measure was sagittal ankle movement (dorsiflexion), measured at initial contact and foot-off and values in stance (max) and swing (min and max). Secondary, frontal ankle movement (in/eversion), foot-progression angle, sagittal knee movement (flexion/extension), sagittal (flexion/extension) and frontal (abd/adduction) hip movement and sagittal (tilt) and frontal (obliquity) pelvic movement were measured. Angles were calculated at initial contact and foot-off. Furthermore, minimal and maximal angles in stance and/or swing phase were calculated for knee, hip and frontal pelvic movement. Results of the affected side are presented in this paper. Besides, spatiotemporal parameters were calculated (see Table A supplemental material for definitions).

### 2.7. Statistical analysis

We did not perform a power-calculation since no data of previous studies measuring timing effects of AFO-provision was available. SPSS version 19 (IBM SPSS Statistics, Chicago, USA) was used for data-analysis. The level of significance for all analyses was set at $p < 0.05$ and normality was checked using the Shapiro-Wilk test. Basic demographic data of the early and delayed group at inclusion were compared: continuous variables were tested using independent samples *t*-tests (normal distribution) or Mann-Whitney *U* tests (non-normal distribution); categorical variables were tested with chi-squared tests or Fisher exact tests, as appropriate. Furthermore, kinematic and spatiotemporal parameters without AFO of the early (week 1) and delayed group (week 9) were compared to detect possible differences between both groups. Independent samples *t*-test or Mann-Whitney *U* test were used, as appropriate.

To calculate effects of AFO-provision, measurements with and without AFO were compared, combining the data of both the early and delayed group. Paired samples *t*-tests were used for normally distributed variables with the kinematic and spatiotemporal parameters as dependent variables and AFO-condition (with and without AFO) as independent variable. Wilcoxon signed-rank tests were conducted for non-normally distributed variables. To study whether timing of AFO-provision (week 1 or 9) influenced the effects, differences between measurements with and without AFO were calculated for both groups separately and these differences were compared. Independent samples *t*-tests were conducted with the differences (with – without AFO) as dependent variable and group as independent variable for normally distributed differences, otherwise, a Mann-Whitney *U* test was conducted.

## 3. Results

### 3.1. Baseline

In total 33 subjects were included. Twenty subjects (eight early, 12 delayed) were included in the analysis as measurements were performed within two weeks after AFO-provision. Fig. 2 details the participant flow through the study. Table 1 shows no statistically significant differences in patient characteristics at inclusion between both groups. On average, measurements were performed 39.8 (9.1) and 90.2 (6.4) days after stroke in the early and delayed group, respectively. Median time between AFO-provision and gait analysis was 10.5 and 2.0 days in the early and delayed group, respectively. The shortest duration between AFO-provision and gait analysis was 1 (early) and 0 (delayed) days. Baseline comparison between the early and delayed group without AFO revealed no significant differences on outcome parameters at the ankle, foot or hip-level or for spatiotemporal parameters (see Table B supplemental material). Significant differences were found for minimal knee flexion during stance (9.2 vs 16.2°; $p = 0.031$), pelvic tilt at initial contact (7.2 vs −1.4°; $p = 0.031$) and foot-off (12.0 vs 6.0°; $p = 0.030$) and pelvic obliquity at initial contact (0.8 vs 4.0°; $p = 0.017$) for the early and delayed group, respectively.

### 3.2. Effect of AFO-provision

Effects of AFO-provision are shown in Table 2 and visually presented in Fig. 3. Significant effects of AFO-provision were found on the ankle-level for all outcome parameters, except for maximal dorsiflexion in stance, see Table 2. Furthermore, foot-progression at initial contact increased significantly after AFO-provision, as did knee and hip flexion at initial contact. Other parameters at the knee and hip-level did not change. No effects on the pelvis were found. Statistically significant effects of AFO-provision were found for cadence (+2.1 steps/min, $p = 0.026$), stride duration (−0.08 s, $p = 0.015$) and single support duration (+1.0%, $p = 0.002$) (Table 2).

### 3.3. Effect of timing

No significant kinematic effects of the timing of AFO-provision were found when effects were compared between the early and delayed group (results shown in supplemental table C). Furthermore, no effects of timing were found for the spatiotemporal parameters, except for a significant effect on single support phase ($p = 0.026$; increase of 0.3% (SD 1.3) from 21.5% to 21.8% (early) vs increase of 1.5% (SD 1.0), from 19.7% to 21.2% (delayed).

## 4. Discussion

Our primary aim was to study the short-term kinematic and spatiotemporal effects of the actual AFO-provision early after stroke. We found significant positive effects on sagittal ankle movement, our primary outcome measure, as plantarflexion angles at initial contact and during swing significantly improved into dorsiflexion angles. Furthermore, inversion angles improved significantly. These changes are clinically relevant because foot-clearance in swing and prepositioning of the foot at initial contact were improved by the AFO. Both phases are considered important prerequisites of gait [20]. Our results show that the indication for

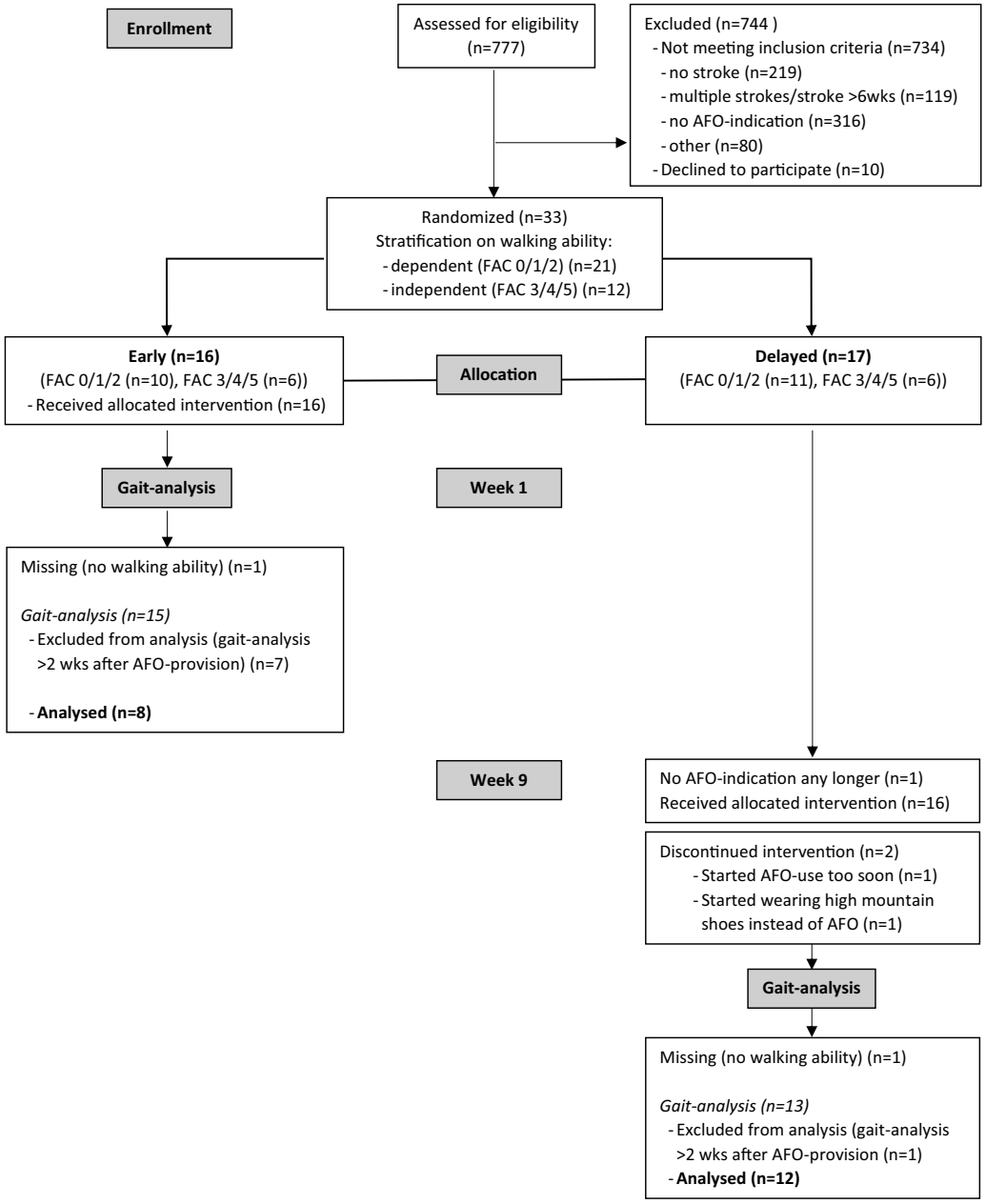


**Fig. 2.** Flowchart.
This figure shows the participant flow through the study.
Abbreviations;: AFO: Ankle-foot orthosis; FAC: Functional Ambulation Categories.

**Table 1**
Patient characteristics at inclusion.

| | | Total (n = 20) | Early (n = 8) | Delayed (n = 12) |
|---|---|---|---|---|
| Sex (male/female)[a] | | 10/10 | 4/4 | 6/6 |
| Age (years)[b] | | 56.0 (9.8) | 57.3 (11.1) | 55.2 (9.3) |
| Height (cm)[c] | | 170.8 (165.6–175.0) | 173.0 (164.0–177.3) | 170.3 (167.6–174.8) |
| Weight (kg)[b] | | 75.8 (14.0) | 80.1 (11.7) | 72.9 (15.1) |
| Time since stroke at inclusion (days)[b] | | 30.0 (6.3) | 27.1 (6.1) | 31.9 (5.9) |
| Affected body side (left/right)[a] | | 12/8 | 5/3 | 7/5 |
| Type of stroke (ischemic/hemorrhagic)[a] | | 16/4 | 7/1 | 9/3 |
| Type of AFO (flexible/semi-rigid/rigid)[a] | | 18/0/2 | 7/0/1 | 11/0/1 |
| Sensation* | Tactile (normal/impaired/absent)[a] | 18/0/2 | 7/0/1 | 11/0/1 |
| | Propriosepsis normal/impaired/absent)[a] | 18/1/1 | 7/0/1 | 11/1/0 |
| Mini-Mental State Examination[c] | | 27.0 (24.5–28.0) | 27.0 (27.0–28.0) | 27.5 (22.3–28.0) |
| Motricity Index, lower limb[c] | | 42.0 (17.5–45.8) | 42.0 (42.0–53.0) | 42.0 (0–42.0) |

Abbreviations: AFO: ankle-foot orthosis. Mean (SD) or median (interquartile range) are presented. [a]fisher exact test (2-tailed); [b]independent samples *t*-test; [c]Mann-Whitney *U* test with median (IQR); [d]pearson chi-squared test. *tested with Erasmus MC modifications to the Nottingham Sensory Assessment, lower limb part.

**Table 2**
Effect of providing AFOs.

| | Effect (N = 20) | | | |
|---|---|---|---|---|
| | Without AFO | With AFO | With AFO – Without AFO | p |
| Kinematics (°) | | | | |
| Ankle | | | | |
| Dorsiflexion at initial contact | −3.6 (7.3) | 3.0 (3.9) | 6.6 (4.0;9.1) | <**0.001**[a] |
| Max. dorsiflexion during stance | 14.1 (6.5) | 14.6 (5.6) | 0.5 (−1.0;2.0) | 0.464[a] |
| Dorsiflexion at foot-off | 0.0 (7.4) | 5.2 (3.7) | 5.2 (2.9;7.6) | <**0.001**[a] |
| Min. dorsiflexion during swing | −6.1 (7.8) | 2.6 (3.5) | 8.7 (5.9;11.5) | <**0.001**[a] |
| Max. dorsiflexion during swing | 3.1 (6.2) | 6.7 (3.9) | 3.7 (2.0;5.3) | <**0.001**[a] |
| Inversion at initial contact | 7.7 (6.1) | 5.5 (2.9) | −2.3 (0.1;4.5) | **0.043**[a] |
| Inversion at foot-off | 7.9 (6.1) | 4.7 (3.5) | −3.2 (0.9;5.5) | **0.009**[a] |
| Foot | | | | |
| Foot-progression at initial contact | −10.0 (−15.5;-8.3) | −13.2 (−18.2;-5.6) | −1.6 (−5.2;-0.9) | **0.014**[b] |
| Foot-progression at foot-off | −16.5 (−31.4;-11.1) | −18.8 (−28.6;-10.1) | −2.3 (−3.8;3.9) | 0.478[b] |
| Knee | | | | |
| Flexion at initial contact | 18.1 (5.7) | 20.4 (6.4) | 2.3 (1.6;3.0) | <**0.001**[a] |
| Min. flexion during stance | 13.4 (7.3) | 14.6 (7.4) | 1.2 (−0.3;2.7) | 0.112[a] |
| Flexion at foot-off | 39.2 (11.8) | 40.6 (9.7) | 1.3 (−0.7;3.3) | 0.179[a] |
| Max. flexion during swing | 42.5 (12.6) | 42.8 (10.3) | 0.3 (−1.5;2.1) | 0.711[a] |
| Hip | | | | |
| Flexion at initial contact | 25.9 (10.7) | 27.4 (10.5) | 1.6 (0.7;2.4) | **0.001**[a] |
| Min. flexion during stance | 3.4 (11.8) | 3.1 (11.8) | −0.3 (−1.5;0.8) | 0.572[a] |
| Flexion at foot-off | 11.1 (6.0;17.6) | 11.1 (3.7;17.6) | −0.3 (−1.5;1.2) | 0.601[b] |
| Max. flexion during swing | 30.0 (10.5) | 30.3 (10.6) | 0.3 (−0.9;1.6) | 0.592[a] |
| Adduction at initial contact | 0.4 (3.4) | 0.2 (3.1) | −0.2 (−0.6;0.3) | 0.426[a] |
| Max. adduction during stance | 3.4 (3.1) | 2.8 (3.1) | −0.6 (−1.2;0.0) | 0.061[a] |
| Adduction at foot-off | −2.6 (3.4) | −2.7 (3.6) | −0.2 (−0.7;0.4) | 0.577[a] |
| Max. adduction during swing | 1.4 (3.3) | 1.1 (3.0) | −0.2 (−0.6;0.1) | 0.106[a] |
| Pelvis | | | | |
| Tilt at initial contact | 1.8 (−2.9;8.6) | 2.3 (−2.0;9.7) | 0.0 (−0.5;1.4) | 0.478[b] |
| Tilt at foot-off | 8.4 (6.2) | 8.2 (6.5) | −0.2 (−0.7;0.4) | 0.541[a] |
| Obliquity at initial contact | 2.7 (3.1) | 2.6 (2.9) | −0.2 (−0.7;0.4) | 0.563[a] |
| Max. obliquity during stance | 3.7 (2.8) | 3.5 (2.7) | −0.2 (−0.6;0.3) | 0.517[a] |
| Obliquity at foot-off | 2.0 (3.6) | 1.7 (3.2) | −0.4 (−1.0;0.2) | 0.190[a] |
| Max obliquity during swing | 4.7 (3.6) | 4.1 (3.0) | −0.6 (−1.3;0.0) | 0.067[a] |
| **Spatiotemporal** | | | | |
| Walking velocity (m/s) | 0.44 (0.22) | 0.46 (0.22) | 0.02 (−0.01;0.05) | 0.112[a] |
| Cadence (steps/min) | 67.1 (21.1) | 69.2 (21.1) | 2.1 (0.3;3.9) | **0.026**[a] |
| Stride length (m) | 0.75 (0.18) | 0.76 (0.17) | 0.01 (−0.1;0.05) | 0.345[a] |
| Step length (m) | 0.41 (0.08) | 0.40 (0.08) | −0.01 (−0.03;0.01) | 0.332[a] |
| Step width (m) | 0.19 (0.16;0.21) | 0.17 (0.15;0.21) | −0.01 (−0.02;0.00) | 0.052[b] |
| Stride duration (s) | 1.97 (0.66) | 1.89 (0.58) | −0.08 (−0.14;-0.02) | **0.015**[a] |
| Stance duration (% gait cycle) | 68.4 (7.2) | 68.5 (6.4) | 0.1 (−1.4;1.6) | 0.877[a] |
| First double support (% gait cycle) | 16.0 (4.0) | 16.7 (3.6) | 0.7 (−0.3;1.7) | 0.149[a] |
| Single support ((% gait cycle) | 20.4 (6.7) | 21.4 (6.3) | 1.0 (0.4;1.6) | **0.002**[a] |
| Second double support (% gait cycle) | 26.5 (22.4;45.8) | 26.9 (21.8;41.5) | −1.2 (−2.6;0.8) | 0.070[b] |
| Swing duration (% gait cycle) | 31.6 (7.2) | 31.5 (6.4) | −0.1 (−1.6;1.4) | 0.877[a] |

Abbreviations: AFO: ankle-foot orthosis. Mean (SD) or median (interquartile range) is presented. [a]Paired samples *t*-test (mean, 95% confidence interval) is presented; [b]Wilcoxon signed-rank test (median (interquartile range)) is presented.

AFO-use was correct in our included population and that the AFO corrected the ankle as expected. Our findings are in line with a review studying effects of AFOs in mainly chronic stroke patients familiar to walking with AFO [13] and literature studying effects of recent AFO-provision on ankle kinematics after recent stroke [14,15]. Walking speed with and without AFO did not change in our study, so this did not confound our results.

On the knee- and hip level we found increased flexion angles at initial contact after AFO-provision. Most studies including hip kinematics did not report any effects [3,14–16,23]. On the knee-level effects of AFOs are inconclusive: both no effects after recent stroke [14–16], and increased knee flexion at initial contact after chronic stroke are reported [24]. Kobayashi et al. [25] used an experimental AFO in patients after stroke to demonstrate that increasing levels of plantarflexion resistance result in increased knee flexion angles in early stance phase. These findings may explain our results, since applying an AFO increases plantarflexion resistance, thereby changing ankle angles at initial contact from plantar flexion to dorsal flexion. This induces forward rotation of the shank pushing the knee joint forward [25], resulting in

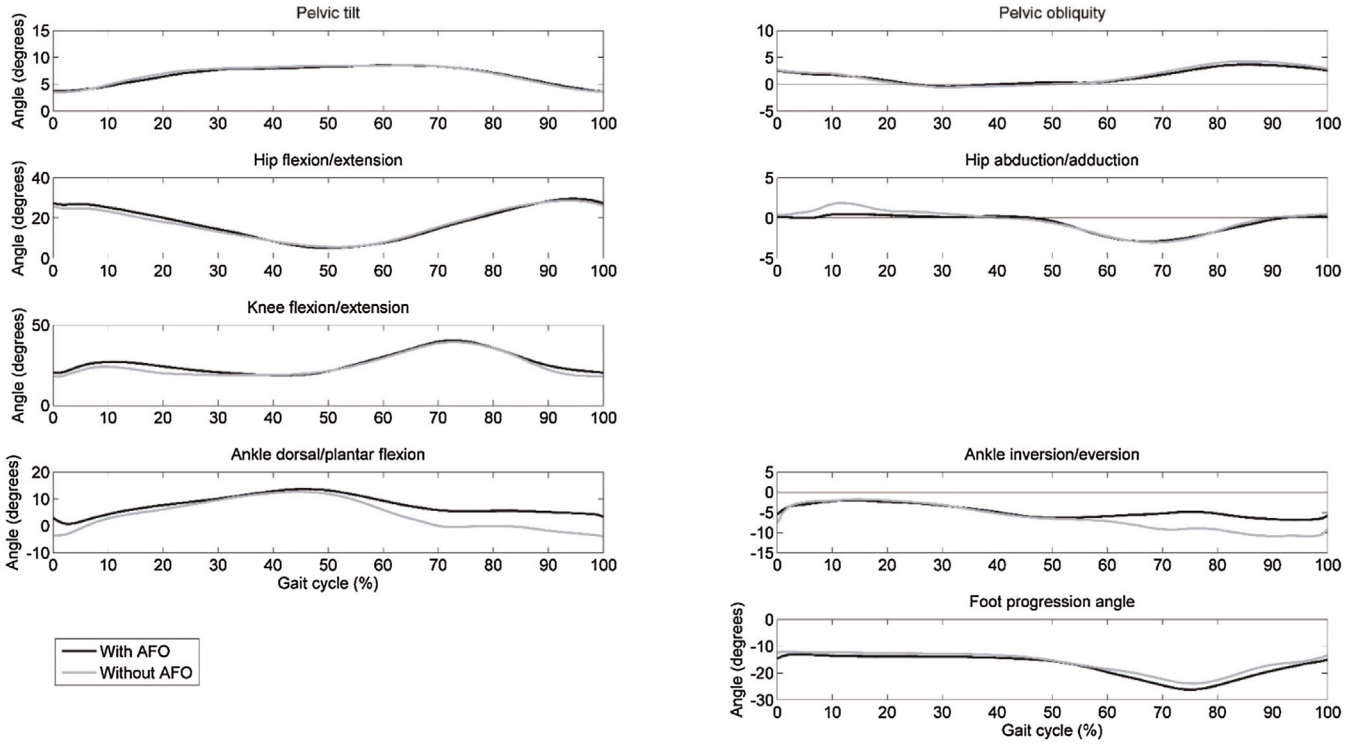


**Fig. 3.** Effect of providing AFOs.
This figure shows the mean kinematics (°) of the affected pelvis, hip, knee, ankle and foot, as % of the gait cycle (N = 20). The data with AFO are shown as a solid black line, the data without AFO are shown as a solid grey line. Anterior pelvic tilt, up pelvic obliquity, hip flexion, hip adduction, knee flexion, ankle dorsiflexion, ankle eversion and internal foot-progression are defined as positive (+).

increased knee flexion at initial contact and also effecting hip flexion.

This is the first randomized controlled trial on effects of early AFO-provision including frontal plane hip kinematics and effects on the pelvis. No effects were found on hip ab/adduction or pelvic tilt (sagittal plane) and obliquity (frontal plane). This means that in our study AFO-provision did not affect possible compensatory movement strategies around hip and pelvis, often mentioned after stroke [7,9–11]. In correspondence with our results, Cruz et al. [10] also reported no effects of AFOs on hip ab/adduction, but they found effects on the pelvis. Chronic stroke patients (50.2 (39.9)) months post-stroke) used to wearing AFOs daily were included in their study. Perhaps effects of removing AFOs in habitual AFO-users after chronic stroke are larger than effects of providing AFOs in subjects after early stroke, or possible compensatory movement patterns were not (yet) developed in our recent stroke subjects. Future analysis of the long-term effects of early AFO-provision on the gait pattern is necessary to give insight in this.

Previous studies often reported positive effects of AFOs on walking speed. This result may be explained by the fact that these studies included chronic stroke patients already using AFOs in daily-life [26,27]. Walking without AFO is probably an unfamiliar situation for these patients. Another explanation may be that subjects in our study may not be completely familiar with walking with AFO, as they were recently provided. Other studies reported positive effects on walking speed in subjects after recent stroke [15,16]. However, differences in study design are observed compared to our study, as anterior and posterior AFO-use while walking barefoot [15], and subjects measured in two different sessions with seven days between measurements using different shoes [16] were studied. Another explanation is that most studies included 5 or 10 m timed walking tests, whereas we used 3D gait-analysis to measure walking speed. It is our clinical observation that walking speed is lower during 3D gait-analysis measurements compared to timed walking tests. This could be explained because subjects were measured in a specialized gait laboratory wearing all kinds of equipment. We speculate that these factors affect walking speed probably more than AFO-provision will affect walking speed, as both Gök et al. [14] and our results show no effects of recent AFO-provision when walking speed is measured during 3D gait-analysis.

Our secondary aim was to study whether timing of AFO-provision post-stroke influenced the short-term effects. We hypothesized that early AFO-provision may be beneficial since the development of compensatory movement patterns in the proximal limb segments may decrease when foot-drop is limited early in the rehabilitation because of early AFO-provision. However, no effects of timing were found for any of the kinematic or spatiotemporal parameters, except for a very small but significant effect on single support phase. Apparently, short-term effects were not influenced by the timing of AFO-provision. Whether or not long-term effects are present is subject for future studies.

An important strength of this study is that we included subjects early after stroke who were not yet used to walking with an AFO. We provided them with an AFO during the study and measured effects within two weeks after provision. These conditions match with AFO-provision in daily clinical practice. Furthermore, to our knowledge, this is the first study on effects of early AFO-provision that included frontal plane hip kinematics and effects on the pelvis. Our findings add new insights to the literature as hip- and pelvis-movements are often mention as important compensatory

strategies in the absence of sufficient dorsiflexion after stroke [6,9,10]. However, in our study no effects of AFOs were found with respect to these compensatory strategies.

There are some limitations to this study. The order of testing with and without AFO was randomized, but unfortunately it was not possible to blind subjects and assessor for AFO-use or early or delayed provision. We found some kinematic differences at baseline between both groups without AFO. However, these differences did not involve our primary outcome measures. Our sample size was limited and not all included subjects could be included in the data-analyses since they were not able to perform the measurements within two weeks after AFO-provision. We could not perform a valid power-calculation to determine sample size because data of previous studies measuring timing-effects of AFO-provision were not available. Therefore, we performed a post-hoc power calculation. For outcome measures with p-values between 0.05 and 0.2 in Table 2 and supplementary table C, we calculated that between 39 and 92 subjects would be needed to find significant differences. However, we would like to point out that it is doubtful whether these effects would be clinically relevant, as in our calculations the kinematic differences were very small (up to 1.3° differences comparing with and without AFO). Power calculation for outcome measures with p-values >0.2 showed that over hundred(s) of subjects would be needed to find significant differences. Therefore, we conclude that for these outcome measures it is unlikely that differences of AFO-provision or timing of AFO-provision exist.

In conclusion, this study showed positive short-term effects of AFO-provision on ankle kinematics in patients early after stroke. Minor effects on knee and hip flexion and spatiotemporal parameters were found. Hip ab/adduction and pelvis movement were not affected. Furthermore, no differences in effects of AFO-provision were found when early and delayed provision (39.8 (9.1) vs. 90.2 (6.4) days) after stroke were compared.

## Contributors

CN: Conception and design of the study, acquisition of data, analysis and interpretation of the data, drafting and final approving the article. MH: Acquisition of data, analysis and interpretation of the data, revising and final approval of the article. JvdP: analysis and interpretation of the data, revising and final approval of the article. HH, JR, JB: conception and design of the study, interpretation of the data, revising and final approving the article.

## Conflicts of interest

The AFOs used in this study were provided by Basko Healthcare, Zaandam, the Netherlands. Basko was not involved in designing the study, collecting data or the analysis and interpretation of data. In addition, they had no role in writing the article and the decision to submit the article for publication.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.gaitpost.2017.03.028.

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