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The influence of early or delayed provision of ankle-foot orthoses on pelvis, hip and knee kinematics in patients with sub-acute stroke: A randomized controlled trial

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ABSTRACT

Background: Compensatory pelvis, hip- and knee movements are reported after stroke to overcome insufficient foot-clearance. Ankle-foot orthoses (AFOs) are often used to improve foot-clearance, but the optimal timing of AFO-provision post-stroke is unknown. Early AFO-provision to prevent foot-drop might decrease the development of compensatory movements, but it is unknown whether timing of AFO-provision affects post-stroke kinematics.

Research questions: 1) To compare the effect of AFO-provision at two different points in time (early versus delayed) on frontal pelvis and hip, and sagittal hip and knee kinematics in patients with sub-acute stroke. Effects were assessed after 26 weeks; 2) To study whether possible changes in kinematics or walking speed during the 26-weeks follow-up period differed between both groups.

Method: An explorative randomized controlled trial was performed, including unilateral hemiparetic patients maximal six weeks post-stroke with indication for AFO-use. Subjects were randomly assigned to AFO-provision early (at inclusion) or delayed (eight weeks later). 3D gait-analysis with and without AFO was performed in randomized order. Measurements were performed in study-week 1, 9, 17 and 26.

Results: Twenty-six subjects (15 early, 11 delayed) were analyzed. After 26 weeks, no differences in kinematics were found between both groups for any of the joint angles, both for the without and with AFO-condition. Changes in kinematics during the 26-weeks follow-up period did not differ between both groups for any of the joint angles during walking without AFO. Significant differences in changes in walking speed during the 26-weeks follow-up were found ($p = 0.034$), corresponding to the first eight weeks after AFO-provision.

Significance: Results indicate that early or delayed AFO-use post-stroke does not influence pelvis, hip and knee movements after 26 weeks, despite that AFO-use properly corrected drop-foot. AFOs should be provided to improve drop-foot post-stroke, but not with the intention to influence development of compensatory patterns around pelvis and hip.

1. Introduction

Insufficient foot-clearance is an important alteration in the gait pattern often seen after stroke. It can be caused by decreased hip [1] and knee flexion [1,2] and decreased ankle dorsiflexion [1,3]. To overcome foot-clearance problems, individual stroke patients may use

compensatory movement strategies like circumduction [2,4], increased hip flexion [3] and pelvic hiking [2,4,5], depending on the patient's specific impairments and chosen strategy. Ankle-foot orthoses (AFOs) are often used to improve walking and are reported to facilitate, amongst others, toe-clearance in swing [6]. In a review, AFOs were found to prevent foot-drop (i.e. plantarflexion) in early stance, swing

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and toe-off [7]. Most of the included studies investigated chronic subjects (> 6 months).

With respect to daily clinical practice, studying effects of AFOs earlier after stroke is relevant, since the optimal timing of AFO-provision after stroke is still unclear [8] and a topic for debate amongst clinicians. On the one hand, AFO-use early post-stroke is reported to improve early mobilization [9]. On the other hand, papers reported that clinicians might fear (early) AFO-use, as this could lead to muscle-disuse. Consequently, delays in recovery and permanent gait impairments are feared [6,10,11]. Clear evidence of the long-term effects of timing of AFO-provision on gait kinematics after stroke is missing.

3D gait-analysis is a powerful tool to quantify joint kinematics during gait [12] and studies assessing kinematic effects of AFOs early post-stroke may contribute to the debate about the optimal timing of AFO-provision. By capturing kinematics, the effects of AFOs on the gait pattern can be quantified. This includes the direct effects on the ankle, but also on more proximal joints like pelvis, hip and knee, which relate to the before mentioned compensatory movements. Previous studies investigating kinematic effects of AFOs in the first months after stroke only compared walking with and without AFO immediately after AFO-provision. Positive effects of AFOs on ankle kinematics [13,14] and walking speed [9,13,14] and no effects on sagittal knee or hip kinematics [9,13,14] were found. Effects of AFOs on frontal pelvis and hip kinematics (i.e. pelvis obliquity and hip abduction) are unknown since these outcomes were not included. However, including these frontal plane measurements to study effects of AFOs early after stroke is relevant, since compensatory movements like circumduction, pelvis obliquity and hip flexion are reported to achieve foot-clearance in case of insufficient dorsiflexion [3–5].

Besides the previously mentioned early mobilization [9], another possible beneficial effect of early AFO-provision might be a decrease in the development of compensatory movements in proximal joints, when foot-drop is limited by AFO-use early after stroke. We recently reported the short-term results of a study focusing on the timing of AFO-provision. Kinematic effects of AFO-provision, including frontal pelvis and hip kinematics were assessed [15]. Positive effects of walking with AFOs on ankle dorsiflexion, but no effects of AFOs on the pelvis and hip were found. A possible explanation for not finding effects might be that compensatory movements at these joint-levels were not developed yet. Subjects were early after stroke and measured within one session. Results of the follow-up measurements to study the effects of timing of AFO-provision over a longer period have not yet been reported.

Therefore, the primary aim of the current paper was to compare the effects of AFO-provision at two different points in time (early versus delayed) on frontal pelvis and hip, and sagittal hip and knee kinematics in patients with sub-acute stroke. Effects were assessed after 26 weeks. We hypothesized that early AFO-provision was beneficial compared to delayed provision with respect to the development of compensatory movements. In the frontal plane, we expected less pelvic obliquity (ipsilateral frontal plane elevation of the pelvis) and less abduction of the ipsilateral limb during swing in the early group compared to the delayed group. In the sagittal plane, we expected less excessive hip and knee flexion during swing.

In a previous publication on the effects of early and delayed AFO-provision on functional outcome measures [16], we found significantly different patterns of recovery during the 26-weeks follow-up period between both groups. Therefore, we also wanted to study whether the patterns of recovery over time in terms of kinematics differed between early and delayed provision. Since walking speed is known to influence gait kinematics [17], we included walking speed in our study. Our secondary aim was to study whether possible changes in kinematics or walking speed during the 26-weeks follow-up period differed between both groups. In analogy with our previous findings on functional outcomes [16], we hypothesized that if any differences appeared between both groups during the 26-weeks follow-up, they appeared at an early point in time (first eight weeks) for the early group, compared to the

delayed group, since the early group was provided with an AFO from the start of the study.

2. Methods

We conducted 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.

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) minimal 18 years; 3) maximal six weeks post-stroke; 4) receiving inpatient rehabilitation care at inclusion; 5) able to follow simple verbal instructions; 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, neglect or cardiac, pulmonary or orthopedic disorders that could interfere with gait were excluded.

2.2. Randomization

An independent person allocated participants to one of two intervention-groups using stratified block-randomization: 1) AFO-provision at inclusion, 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 before randomization.

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). AFO-fitting was performed by a licensed orthotist. AFO-type was chosen according to a custom developed protocol [20]. After AFO-provision, subjects were instructed to use the AFO throughout the day, including during their stay at the ward, during therapies and when subjects went home. After AFO-provision, special attention was paid to possible pressure marks by the rehabilitation physician. Besides the AFO-intervention, all subjects received usual care from experienced physiotherapists according to the Dutch guidelines for physiotherapy after stroke [21].

2.4. Procedures

3D gait-analysis was performed four times in both groups: in week 1, 9, 17 and 26 of the study (T1, T2, T3 and T4, respectively). T1 and T2 correspond with the point in time at which the AFO was provided in both groups. The eight weeks between T1 and T2 were also incorporated between T2 and T3, T4 was planned as follow-up measurement after 26 weeks, since most improvements after stroke are observed within the first six months after stroke [22]. The measurements required that subjects were able to walk without physical support of another person (FAC \geq 3) and had sufficient endurance to complete the measurement. If this was not the case, the measurement was postponed until these requirements were met. All measurements were performed with and without AFO in randomized order. The delayed

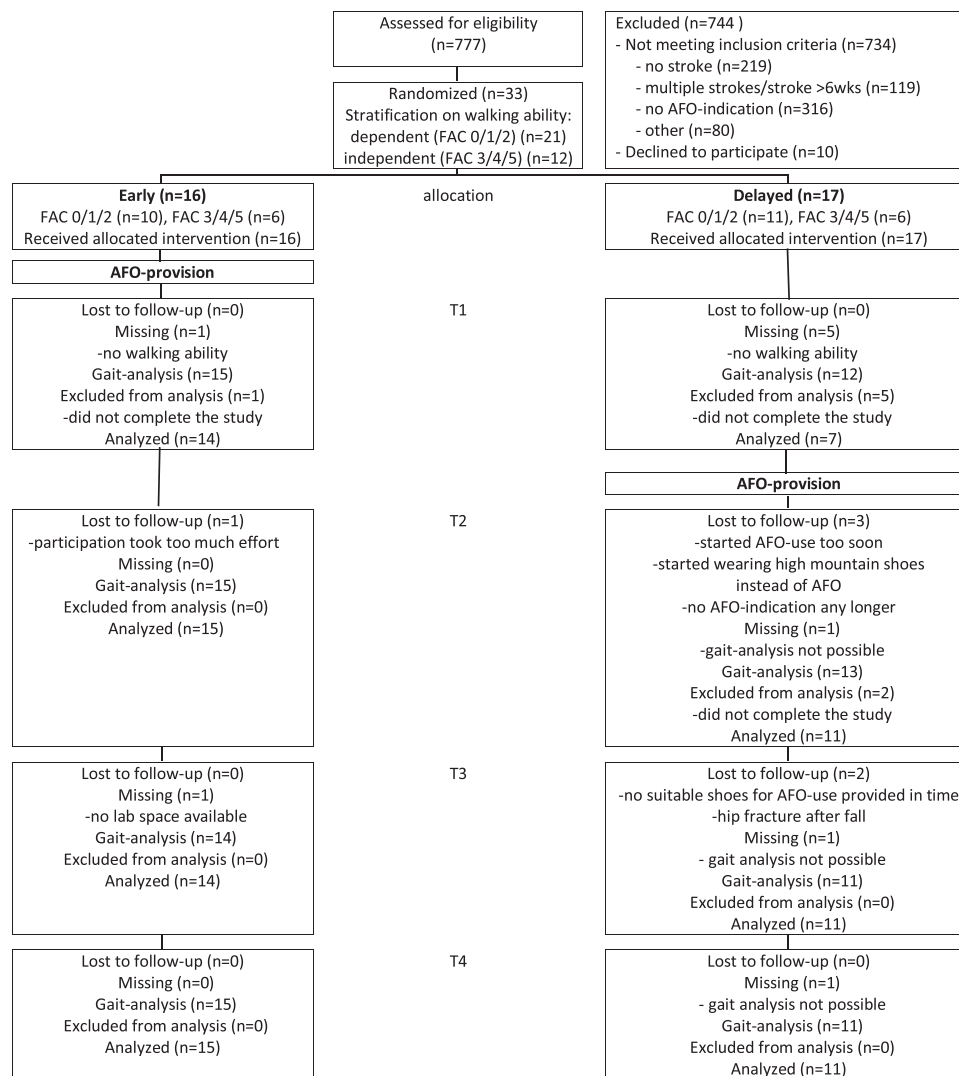


Fig. 1. CONSORT-flowchart.

The figure shows the participant flow through the study.

Abbreviations: AFO: ankle-foot orthosis; FAC: Functional Ambulation Categories.

group did not use AFOs at T1 and were therefore measured without AFO only at T1.

2.5. Data collection and processing

At inclusion, basic demographic data were recorded. Whether the AFO was actually used in the period before the measurement was assessed during every gait analysis-measurement. Motion data were collected at 100 Hz in a gait-laboratory, using a six-camera Vicon MX13 + motion-analysis system (Vicon, Oxford, UK). Reflective 25-millimeter markers were placed on the skin and shoes according to the modified Helen-Hayes marker set. Two additional markers were placed on each shoe at metatarsal I and V to assess in/eversion movements. Subjects walked on a level walkway over a distance of eight meters at self-selected walking speed, wearing their own shoes. Markers were not removed between measurements with and without AFO. Assistive devices (such as cane or quad stick) were permitted.

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 effects of AFOs on compensatory movements in proximal joints can only be assessed under the assumption that the AFO sufficiently corrects the ankle. We previously reported that AFOs properly corrected drop-foot on the short-term [15]. To confirm effects in the long-term, ankle kinematics were included in the current study as well.

Pelvic obliquity, hip ab/adduction and hip and knee flexion/extension at week 26 were defined as primary outcome measures. Frontal plane pelvic obliquity and hip ab/adduction both contribute to the circumduction-movement. Together with hip and knee flexion/extension (both sagittal plane), these movements are responsible for the main compensatory movements to improve foot-clearance after stroke in case of drop-foot and therefore could be affected by AFO-provision.

Walking speed was assessed by calculating the mean speed of the anterior superior iliac spine-markers along the axis of progression.

For all angles, minimal and maximal values in swing, and values at initial contact and foot-off were calculated. Only results of the affected side are presented in this paper.

2.7. Statistical analysis

SPSS version 19 (IBM SPSS Statistics, Chicago, USA) was used for data-analysis. Normality was checked visually and using the Shapiro-Wilk test. Assuming interdependence among joints, the level of significance for analysing kinematics related to the primary and secondary aim were corrected for multiple testing at similar phases of gait using the Holm-Bonferroni correction. For other analyses (like baseline demographics, walking speed) the level of significance was set at $p < 0.05$. A power-calculation could not be performed since data of previous studies measuring timing effects of AFO-provision was not available.

Basic demographic data of both groups at inclusion were compared using independent samples *t*-test/Mann-Whitney *U* test for continuous and chi-squares test/Fisher exact test for categorical variables, as appropriate. Kinematics at T1 without AFO were compared to detect possible baseline differences between both groups. For this, independent samples *t*-test or Mann-Whitney *U* test were used, as appropriate.

To confirm whether the AFO properly corrected drop-foot, a *within-group* analysis comparing ankle dorsi/plantarflexion data with and without AFO at T4 was performed for both groups. Paired samples *t*-test or Wilcoxon signed-rank tests were used, as appropriate.

To study our primary aim, the effects after 26 weeks were compared using *between-group* analysis of data at T4. Independent samples *t*-tests or Mann-Whitney *U* tests were used, as appropriate.

To study our secondary aim, whether changes in kinematics or walking speed during the 26-weeks follow-up period differed between both groups, a mixed-model repeated measures analysis was performed to compare group-by-time interactions.

The primary analysis only included data after 26 weeks (T4). This analysis was performed both without and with AFO. The secondary analysis included data of all four measurements (T1, T2, T3 and T4). Since data of four measurements was only available without AFO (the delayed group did not use an AFO at T1 yet), the mixed-model repeated measures analysis was only performed for data without AFO.

3. Results

3.1. Baseline

Fig. 1 details the participant-flow through the study. In total 33 subjects (16 early, 17 delayed) were included in the study. Of these, 26 subjects (15 early, 11 delayed) were included in the analysis. Six subjects (one early, five delayed) did not complete the study (drop-out after T1 or T2). They were not included in the analysis since their data was insufficient to answer the research questions (missing T4). One additional subject (delayed) is missing since performing a 3D gait-analysis was not possible (measurements were too tiring). Of the 26 included subjects, five (one early, four delayed) were not able to perform T1, as they were not able to walk without physical support of another person and/or had insufficient endurance to complete T1. Data of one subject in the early group is missing at T3 because no lab-space was available.

Table 1 shows the subject characteristics. No statistically significant differences at inclusion were found between both groups. Most subjects were provided with a flexible type of AFO (see Table 1). Of them, one subject (early group) changed from a flexible to a semi-rigid AFO in the period after T1, as rehabilitation physicians judged that the flexible AFO did not provide enough support anymore. All subjects used their AFO daily at the time of the gait-analysis at T1, T2, T3 and T4, except for three subjects (two early, one delayed) at T4. These three subjects used their AFO regularly (during some days of the week), but not daily (every day) at T4. However, they were measured both with and without AFO at T4.

Baseline comparison of kinematics and walking speed of subjects performing at T1 without AFO between the early ($N = 14$) and delayed

Table 1
Subject characteristics.

	Total (n = 26)	Early (n = 15)	Delayed (n = 11)
Sex (male/female) ^a	17 / 9	10 / 5	7 / 4
Age (years) ^b	56.4 (9.8)	57.0 (9.9)	55.6 (10.1)
Height (cm) ^c	174.0 (169.8; 179.0)	174.0 (169.0;179.0)	171.0 (170.0;178.0)
Weight (kg) ^b	81.1 (12.5)	84.4 (11.4)	76.5 (12.8)
Time since stroke at inclusion (days) ^b	30.4 (6.3)	29.1 (6.5)	32.2 (6.0)
Affected body side (left/right) ^a	16 / 10	8 / 7	8 / 3
Type of stroke (ischemic/ hemorrhagic) ^a	22 / 4	14 / 1	8 / 3
Type of AFO provided (flexible/ semi-rigid/rigid) ^a	23 / 0 / 3	13 / 0 / 2	10 / 0 / 1
Sensation ^a			
Tactile (normal/ impaired/absent) ^a	21 / 2 / 3	12 / 1 / 2	9 / 1 / 1
Proprioception (normal/ impaired/absent) ^a	21 / 4 / 1	12 / 2 / 1	9 / 2 / 0
Mini-Mental State Examination ^c	27.0 (24.8;28.0)	27.0 (25.0;28.0)	28.0 (24.0;28.0)
Motricity Index, lower limb ^c	39.5 (10.5;42.0)	37.0 (18.0;42.0)	42.0 (0.0;42.0)
Time since stroke at gait analysis (days)			
T1 ^b	51.6 (15.3) (n = 21)	51.3 (16.1) (n = 14)	52.1 (14.9) (n = 7)
T2 ^b	90.8 (7.4) (n = 26)	90.1 (6.5) (n = 15)	91.8 (8.7) (n = 11)
T3 ^b	146.0 (6.5) (n = 25)	146.8 (7.4) (n = 14)	145.1 (5.5) (n = 11)
T4 ^c	209.7 (7.0) (n = 26)	209.4 (7.4) (n = 15)	210.1 (6.6) (n = 11)

Gait analysis were planned in week 1 (T1), 9 (T2), 17 (T3), and 26 (T4) of the study, but measurements were postponed in case subjects were not able to walk without physical support of another person and/or had insufficient endurance to complete a gait analysis measurement. The time since stroke (days) at which gait analysis was performed was reported.

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).

* tested with Erasmus MC modifications to the Nottingham Sensory Assessment, lower limb part.

($N = 7$) group revealed no significant differences.

3.2. Ankle dorsi/plantarflexion

Ankle dorsi/plantarflexion angles without and with AFO are presented in Tables 2 and 3, respectively. In general, the ankle showed plantarflexion angles without AFO, whereas with AFO dorsiflexion angles were found. *Within-group* analysis comparing walking with and without AFO at T4 showed significant effects of AFO-provision for both the early and delayed group (p between ≤ 0.001 and $p = 0.048$), confirming proper correction of drop-foot by the AFO at T4.

3.3. Effect after 26 weeks

Table 2 (without AFO) and Table 3 (with AFO) show pelvis, hip, and knee kinematics and walking speed of the early and delayed group at T1, 2, 3 and 4. Fig. 2a and b show the frontal pelvis and hip, and sagittal hip and knee movement during the gait cycle, respectively without and with AFO.

The lowest p -value should be ≤ 0.008 (α of 0.05 / 6 joint-levels) in order to be statistically significant after Holm-Bonferroni correction. After 26 weeks (T4), *between-group* analysis showed no statistically

Table 2
Mean (SE) scores without AFO for the early (T1-T4) and delayed (T1-T4) group; the between group-differences at T4, and the overall group x measurement interaction.

	Early Mean (SE)				Delayed Mean (SE)				Independent samples t-test			Mixed-model repeated measures analysis	
									ΔT4 Early group – Delayed group (95% CI)	p-value	Group*measurement interaction	p-value	
	T1 (N = 14)	T2 (N = 15)	T3 (N = 14)	T4 (N = 15)	T1 (N = 7)	T2 (N = 11)	T3 (N = 11)	T4 (N = 11)					
Kinematics (°)													
Pelvis													
Obliquity at foot-off	1.4 (0.8)	3.0 (0.8)	2.7 (1.0)	1.7 (0.9)	2.5 (1.1)	3.4 (0.9)	3.2 (1.2)	2.8 (1.0)	-1.0 (-3.8;1.7)	0.448	0.859		
Min. obliquity during swing	0.7 (0.8)	1.9 (0.7)	1.7 (0.9)	0.7 (0.8)	2.3 (1.1)	3.1 (0.8)	2.0 (1.0)	2.1 (1.0)	-1.4 (-4.0;1.2)	0.280	0.602		
Max. obliquity during swing	4.0 (0.7)	5.6 (0.9)	5.4 (1.1)	4.6 (1.0)	5.0 (1.0)	6.2 (1.0)	5.8 (1.3)	5.1 (1.2)	-0.5 (-3.7;2.7)	0.770	0.975		
Obliquity at initial contact	1.6 (0.7)	2.8 (0.8)	2.4 (0.9)	1.4 (0.8)	3.3 (1.0)	4.0 (0.9)	2.9 (1.0)	2.3 (1.0)	-0.8 (-3.5;1.8)	0.523	0.769		
Hip													
Adduction at foot-off	-2.5 (0.7)	-1.7 (1.0)	-2.0 (1.2)	-2.9 (1.1)	-3.1 (0.9)	-3.0 (1.2)	-3.6 (1.4)	-4.8 (1.3)	1.9 (-1.7;5.4)	0.292	0.877		
Min. adduction during swing	-3.6 (0.7)	-2.9 (0.9)	-3.9 (1.2)	-4.7 (1.0)	-3.8 (0.9)	-4.2 (1.1)	-4.9 (1.3)	-6.5 (1.1)	1.8 (-1.3;4.9)	0.239	0.584		
Max. adduction during swing	0.7 (0.6)	1.6 (0.8)	1.2 (1.0)	-0.3 (1.0)	-0.2 (0.9)	0.1 (1.0)	-1.3 (1.1)	-2.7 (1.2)	2.4 (-0.8;5.6)	0.128	0.823		
Adduction at initial contact	-0.2 (0.7)	0.9 (0.8)	0.6 (1.0)	-1.5 (1.0)	-1.5 (1.0)	-0.8 (1.0)	-2.9 (1.1)	-4.0 (1.2)	2.5 (-0.7;5.7)	0.119	0.588		
Knee													
Flexion at foot-off	16.0 (2.5)	10.0 (2.4)	10.5 (2.3)	8.4 (2.7)	11.8 (3.2)	10.0 (2.8)	9.9 (2.7)	6.8 (3.1)	1.6 (-6.9;10.0)	0.703	0.459		
Min. flexion during swing	15.8 (2.5)	9.6 (2.5)	9.6 (2.4)	7.8 (2.7)	11.7 (3.2)	9.8 (2.8)	9.6 (2.8)	6.8 (3.1)	1.0 (-7.5;9.6)	0.807	0.458		
Max. flexion during swing	30.7 (2.5)	28.9 (2.6)	27.6 (2.5)	27.2 (2.3)	26.4 (3.0)	26.3 (3.0)	26.4 (2.9)	24.0 (2.7)	3.2 (-4.1;10.5)	0.372	0.750		
Flexion at initial contact	28.0 (2.5)	26.9 (2.5)	25.7 (2.3)	25.6 (2.2)	22.1 (3.1)	22.0 (2.9)	22.8 (2.7)	21.0 (2.6)	4.6 (-2.4;11.6)	0.188	0.818		
Ankle													
Flexion at foot-off	35.5 (3.3)	38.1 (2.9)	37.2 (3.5)	37.1 (3.4)	34.7 (4.0)	37.2 (3.4)	36.7 (4.1)	38.2 (4.0)	-1.1 (-11.9;9.8)	0.843	0.887		
Min. flexion during swing	13.9 (1.5)	13.9 (1.9)	12.4 (1.9)	14.0 (1.8)	18.1 (2.1)	18.9 (2.2)	17.6 (2.1)	15.6 (2.1)	-1.6 (-8.1;4.9)	0.604	0.303		
Max. flexion during swing	39.0 (3.4)	43.0 (3.3)	41.1 (3.8)	41.1 (3.8)	35.9 (4.1)	39.0 (3.9)	38.7 (4.4)	40.9 (4.8)	0.938 ^a	0.723 ^b			
Flexion at initial contact	15.4 (1.4)	16.3 (1.8)	14.4 (1.7)	15.4 (1.5)	19.6 (1.9)	20.0 (2.1)	20.2 (1.9)	18.7 (1.8)	-3.3 (-8.2;1.6)	0.175	0.474		
Swing													
Dorsiflexion at foot-off	-2.6 (2.3)	-3.0 (2.3)	-2.1 (2.4)	-0.1 (2.3)	-0.3 (3.0)	1.6 (2.7)	-0.2 (2.7)	-3.0 (2.7)	2.9 (-5.5;11.3)	0.485	0.082		
Min. dorsiflexion during swing	-9.2 (2.4)	-10.7 (2.4)	-8.3 (2.4)	-7.7 (2.4)	-6.0 (3.0)	-4.8 (2.8)	-6.2 (2.8)	-8.0 (2.8)	0.3 (-8.9;9.6)	0.937	0.131		
Max. dorsiflexion during swing	0.8 (2.0)	1.3 (1.8)	1.9 (2.0)	4.0 (2.3)	1.9 (2.5)	2.9 (2.1)	1.5 (2.3)	0.4 (2.7)	3.6 (-4.6;11.9)	0.362	0.226		
Initial Contact													
Dorsiflexion at initial contact	-6.1 (2.1)	-6.2 (1.9)	-4.6 (2.0)	-3.4 (2.4)	-4.3 (2.6)	-3.3 (2.3)	-3.9 (2.3)	-4.4 (2.8)	1.0 (-6.5;8.4)	0.793	0.452		
Inversion													
Min. inversion during swing	6.9 (1.5)	6.1 (1.4)	4.8 (1.8)	6.0 (1.5)	7.0 (1.9)	8.3 (1.7)	8.7 (2.1)	7.6 (1.7)	-1.7 (-3.0;6.3)	0.465	0.580		
Max. inversion during swing	11.1 (1.5)	10.5 (1.1)	9.1 (1.6)	9.7 (1.5)	11.6 (1.9)	13.2 (1.3)	14.2 (1.8)	13.2 (1.8)	-3.6 (-1.2;8.4)	0.138	0.271		
Inversion at initial contact	5.1 (1.2)	3.5 (1.2)	3.0 (1.7)	3.7 (1.5)	6.0 (1.6)	7.7 (1.3)	7.8 (2.0)	6.1 (1.7)	-2.5 (-2.1;7.1)	0.280	0.221		
Walking speed (m/s)	0.36 (0.05)	0.53 (0.07)	0.57 (0.07)	0.60 (0.08)	0.35 (0.07)	0.39 (0.08)	0.51 (0.08)	0.57 (0.09)	0.03 (-0.21;0.26)	0.823	0.034		

^a Mann-Whitney U test.

^b data not normally distributed, nevertheless group*measurement interaction has been presented.

Table 3
Mean (SE) scores with AFO for the early (T1-T4) and delayed (T2-T4) group and the between group-difference at T4.

With AFO	Early Mean (SE)				Delayed Mean (SE)			Independent samples t-test	
	T1 (N = 14)	T2 (N = 15)	T3 (N = 14)	T4 (N = 15)	T2 (N = 11)	T3 (N = 11)	T4 (N = 11)	ΔT4 Early group – Delayed group (95% CI)	p-value
Kinematics (°)									
Pelvis									
Obliquity at foot-off	1.3 (1.4)	2.1 (0.7)	2.5 (0.9)	1.2 (0.8)	3.0 (0.8)	2.8 (1.1)	1.9 (0.9)	-0.6 (-3.1;1.8)	0.586
Min. obliquity during swing	0.5 (0.9)	1.1 (0.6)	1.1 (0.8)	-0.1 (0.7)	2.6 (0.7)	2.0 (1.0)	1.4 (0.8)	-1.5 (-3.6;0.7)	0.179
Max. obliquity during swing	3.7 (0.7)	5.0 (0.8)	5.1 (1.0)	4.1 (0.8)	5.5 (0.9)	5.5 (1.1)	4.6 (1.0)	-0.6 (-3.3;2.1)	0.666
Obliquity at initial contact	1.4 (0.7)	2.2 (0.7)	2.1 (0.9)	0.8 (0.8)	3.9 (0.8)	2.9 (1.0)	2.2 (0.9)	-1.4 (-3.8;1.0)	0.241
Hip									
Adduction at foot-off	-2.6 (0.6)	-1.7 (1.0)	-1.7 (1.1)	-3.0 (1.1)	-3.1 (1.2)	-3.7 (1.3)	-4.7 (1.3)	1.7 (-1.8;5.2)	0.318
Min. adduction during swing	-3.7 (0.7)	-3.1 (0.9)	-3.7 (1.0)	-4.8 (0.9)	-4.2 (1.1)	-4.7 (1.2)	-6.1 (1.1)	1.3 (-1.7;4.3)	0.392
Max. adduction during swing	1.1 (0.5)	1.5 (0.8)	1.7 (1.0)	0.3 (1.0)	-0.1 (0.9)	-1.1 (1.1)	-2.1 (1.2)	2.4 (-0.8;5.6)	0.135
Adduction at initial contact	-0.4 (0.7)	0.1 (0.8)	0.3 (0.9)	-1.9 (0.9)	-1.0 (0.9)	-2.4 (1.1)	-3.3 (1.1)	1.4 (-1.5;4.3)	0.323
Flexion at foot-off	15.8 (2.5)	9.7 (2.5)	9.4 (2.2)	8.0 (2.4)	10.3 (2.9)	8.2 (2.6)	5.1 (2.8)	2.9 (-4.8;10.6)	0.440
Min. flexion during swing	15.1 (2.5)	8.8 (2.5)	8.8 (2.2)	7.6 (2.4)	10.3 (2.9)	7.9 (2.6)	4.9 (2.8)	2.7 (-5.0;10.4)	0.477
Max. flexion during swing	31.1 (2.6)	29.3 (2.5)	28.7 (2.4)	28.3 (2.2)	26.4 (2.9)	26.5 (2.8)	24.7 (2.6)	3.7 (-3.3;10.6)	0.285
Flexion at initial contact	29.7 (2.4)	28.4 (2.5)	27.3 (2.3)	27.3 (2.0)	23.7 (2.9)	24.2 (2.7)	22.7 (2.4)	4.7 (-1.9;11.2)	0.155
Knee									
Flexion at foot-off	34.7 (3.0)	36.5 (3.2)	36.8 (3.3)	37.0 (3.5)	38.7 (3.7)	38.3 (3.9)	38.1 (4.1)	-1.1 (-12.1;10.0)	0.845
Min. flexion during swing	14.9 (1.6)	14.7 (1.6)	13.4 (1.6)	14.8 (1.6)	21.4 (1.9)	19.2 (1.9)	16.8 (1.9)	-2.0 (-7.6;3.5)	0.460
Max. flexion during swing	37.6 (3.2)	40.9 (3.7)	41.1 (3.8)	40.9 (4.1)	39.7 (4.3)	40.8 (4.4)	41.0 (4.8)	-0.1 (-13.2;13.0)	0.987
Flexion at initial contact	16.4 (1.7)	16.3 (1.6)	15.3 (1.7)	16.6 (1.6)	22.8 (1.9)	21.1 (1.9)	19.3 (1.9)	-2.7 (-7.9;2.5)	0.302
Ankle									
Dorsiflexion at foot-off	4.4 (0.9)	3.2 (1.1)	2.7 (1.1)	3.4 (1.5)	5.2 (1.3)	3.8 (1.3)	3.8 (1.8)	-0.4 (-5.2;4.4)	0.878
Min. dorsiflexion during swing	1.3 (1.0)	-0.5 (1.0)	-0.4 (1.0)	0.3 (1.4)	2.5 (1.1)	0.7 (1.2)	1.0 (1.7)	-0.7 (-5.7;4.3)	0.769
Max. dorsiflexion during swing	5.6 (1.1)	5.2 (1.1)	5.0 (1.2)	6.1 (1.7)	6.2 (1.3)	5.3 (1.4)	5.6 (1.9)	0.5 (-4.8;5.8)	0.850
Dorsiflexion at initial contact	1.6 (1.2)	0.7 (1.1)	0.6 (1.3)	1.7 (1.6)	2.2 (1.3)	0.9 (1.5)	1.3 (1.9)	0.4 (-4.7;5.4)	0.874
Inversion at foot-off	4.0 (1.0)	3.8 (0.9)	2.8 (1.0)	2.0 (0.9)	5.7 (1.0)	4.5 (1.2)	3.6 (1.0)	-1.6 (-1.1;4.4)	0.239
Min. inversion during swing	5.9 (1.0)	6.1 (0.8)	5.2 (0.9)	4.3 (0.9)	7.9 (0.9)	7.4 (1.0)	6.4 (1.1)	-2.1 (-0.9;5.1)	0.161
Max. inversion during swing	3.0 (0.9)	2.9 (0.8)	1.7 (0.9)	1.0 (0.8)	5.0 (1.0)	3.6 (1.0)	2.4 (0.9)	-1.4 (-1.1;3.8)	0.256
Inversion at initial contact	3.9 (1.0)	4.3 (0.7)	3.5 (0.7)	2.1 (0.9)	6.1 (0.8)	4.7 (0.8)	4.0 (1.1)	-1.8 (-1.1;4.8)	0.213
Walking speed (m/s)	0.37 (0.04)	0.56 (0.07)	0.59 (0.07)	0.64 (0.08)	0.40 (0.08)	0.58 (0.08)	0.63 (0.09)	0.01 (-0.23;0.25)	0.932

Note: data with AFO in the delayed group at T1 is not available since these subjects were not provided with an AFO yet.

significant differences between both groups for any of the joint angles. This was found for walking without (Table 2) and with AFO (Table 3).

No differences in walking speed were found between both groups at T4, both without (Table 2) and with AFO (Table 3).

3.4. Changes during the 26-weeks follow-up

Mixed-model repeated measures analysis showed that changes in kinematics during the 26-weeks follow-up did not differ between both groups for any of the joint-levels during walking without AFO (Table 2).

Significant differences in changes in walking speed during the 26-weeks follow-up were found between both groups ($p = 0.034$), see Table 2. Both groups showed the greatest increase in walking speed during the first period of eight weeks in which they used their AFO (i.e. from T1-T2 (early) and from T2-T3 (delayed)). In these periods, walking speed without AFO increased from 0.36 to 0.53 m/s and from 0.39 to 0.51 m/s, respectively.

4. Discussion

Our primary aim was to compare the effects of AFO-provision at two different points in time (early or delayed) on frontal pelvis and hip, and sagittal hip and knee kinematics in patients with sub-acute stroke. We performed a *between-group* comparison, comparing the effects of early and delayed AFO-provision at 26 weeks. Secondly, we studied whether changes in kinematics and walking speed during the 26-weeks follow-up period differed between both groups.

After 26 weeks, we expected less upward pelvic obliquity and abduction in the frontal plane, and less hip and knee flexion in the sagittal plane in the early group. However, no significant differences between both groups were found, in both the without and with-AFO condition. This means that, against our expectations, early corrections of drop-foot in the distal part of the lower limb with an AFO did not influence movements in the proximal joints (i.e. pelvis, hip and knee) at 26 weeks.

In agreement with previous studies [5,23], our study population showed pelvic upward obliquity (pelvic elevation) in swing, combined with hip abduction, both without and with AFO. The most striking deviation comparing our results with healthy individuals is found in pelvic obliquity, as normally a pelvic drop is present during swing [23,24], see Fig. 2. Furthermore, hip abduction in swing was somewhat less than normal, which can be explained by the upward pelvic obliquity we found. This combination of pelvic upward obliquity and hip abduction is previously reported [23]. These findings indicate that although both groups did not differ in pelvic obliquity and hip abduction angles, deviations from normal gait were present. In the sagittal plane, we expected less excessive hip and knee flexion in the early group due to early AFO-provision. We found maximal hip and knee flexion angles in swing around 25°-30° and 35°-40° (table 2 and 3), respectively. For hip flexion this is within, and for knee flexion this is below the values for healthy subjects [24], see Fig. 2. This indicates that excessive hip and knee flexion were not present as compensatory movement patterns in our population.

Secondarily, we studied whether possible changes in kinematics or

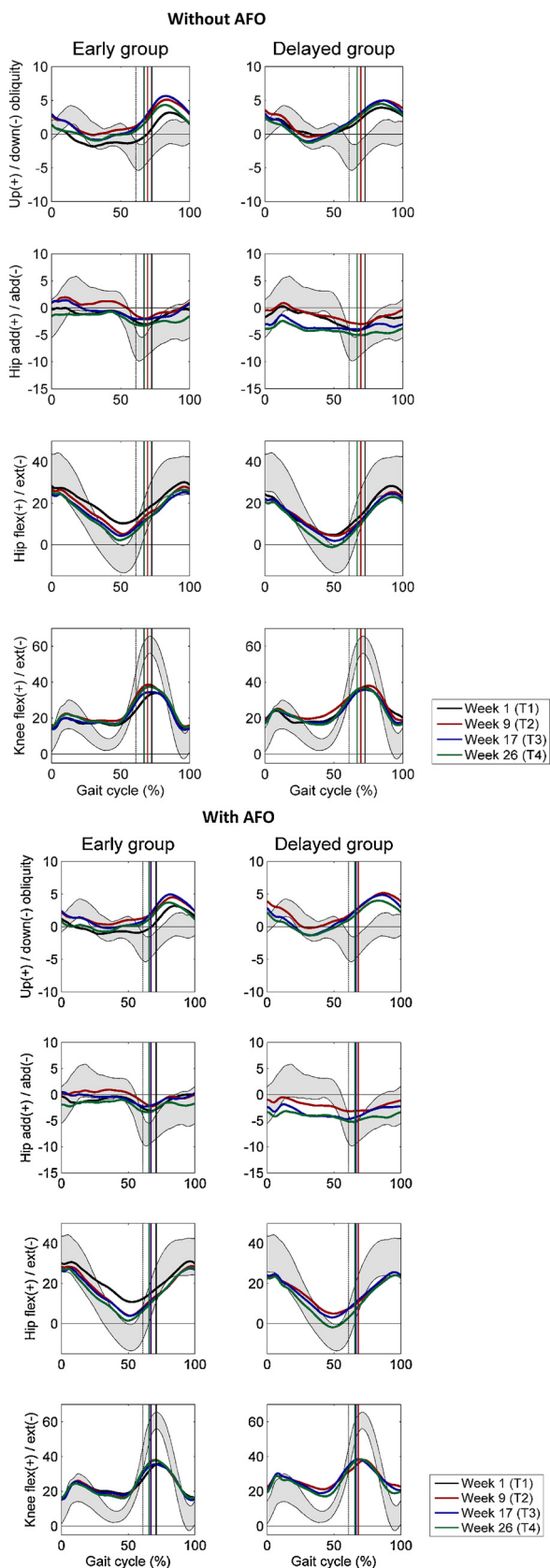


Fig. 2. The figure shows the mean kinematics (°) of the affected pelvis and hip in the frontal, and the hip and knee in the sagittal plane without (Fig. 2a) and with (Fig. 2b) AFO, as % of the gait cycle. The early group (left) and delayed group (right) are depicted. Results of measurements at week 1 (T1), 9 (T2), 17 (T3) and 26 (T4) are shown. The vertical lines represent foot-off. For reference, kinematic values (mean \pm SD) and foot-off (dashed vertical line) of nine healthy elderly (mean age 60.9 (SD3.4) years) are depicted in grey. Subjects walked at comfortable walking speed in our own lab.

previous findings on functional outcomes in the same subjects, we expected that in case differences during the 26-weeks follow-up period would appear between groups, they would appear in the beginning (first eight weeks) of the study [16]. However, we did not find any significant different changes in kinematics during the 26-weeks follow-up between both groups without AFO. We already reported that different timing of AFO-provision had no short-term effects [15]. Together with our current findings, we must conclude that AFO-provision at different points in time does not affect the development of compensatory movements in the short-term, as well as in the long-term. In contrast to the kinematics, we did find significant differences in changes in walking speed during the 26-weeks follow-up comparing both groups ($p = 0.034$) without AFO. The changes correspond to the first eight weeks after AFO-provision ($+ 0.17$ m/s from T1-T2 (early) and $+ 0.12$ m/s from T2-T3 (delayed)). Post-hoc *within-group* analysis showed that the increase in walking speed in the first eight weeks after AFO-provision was statistically significant ($p \leq 0.041$ for all analyses) in both groups, with and without AFO. According to Perera et al. [25] these increases can be considered clinically relevant significant.

The results of our study contain valuable information for clinicians in relation to the discussion whether to provide an individual subject with an AFO earlier or later after stroke. If the goal of AFO-provision is to improve drop-foot in order to prevent development of compensatory movement patterns around pelvis and hip, we did not find any evidence that early AFO-use is beneficial, since no differences were found with the delayed group, who started using their AFOs eight weeks later. The upward pelvic obliquity combined with hip abduction found in our subjects can help to swing the affected leg forward. Because these kinematic patterns were present in both groups right from the start, one can discuss whether these frontal pelvis and hip movements are actually compensatory movement patterns. Compensatory movements suggest that these movements can be voluntarily controlled, which apparently, they cannot. As an alternative, these frontal plane movements may be an integral part of the gait pattern after stroke, as was also mentioned by Kerrigan et al. [23] suggesting these movements as intrinsic abnormalities directly associated with upper motor neuron injury. Future research on this topic is needed, including the contribution of the unaffected leg to the gait pattern after stroke, and the effects of timing of AFO-provision on muscle activation patterns to study whether or not AFO-provision affects muscle activation patterns in the long-term.

Although early AFO-provision may not be beneficial with respect to kinematics of the pelvis, knee and hip, other, for patients and clinicians relevant outcome measures may benefit from early AFO-provision. Direct effects of AFOs on ankle kinematics were found in the current study, changing the ankle from plantarflexion into dorsiflexion (i.e. improve drop-foot) during swing. Drop-foot is reported to contribute to high fall-risk [26], and by improving drop-foot AFOs may reduce fall-risk [27]. Furthermore, we previously found beneficial functional effects of early AFO-provision [16]. Based on the current study, the achievements on functional gains do not seem to be related to kinematics. This raises the question how these functional improvements after stroke are achieved. Again, the contribution of the unaffected limb may play an important role and should be included in future research.

To the best of our knowledge, this is the first study incorporating longitudinal 3D gait-analysis to measure effects of timing of AFO-provision. This is an important strength of the current study. Previous

walking speed during the 26-weeks follow-up period differed between the early and delayed group. Subjects were measured four times in a period of 26 weeks to assess changes over time. In analogy with

longitudinal studies on the effects of AFOs after stroke are lacking 3D gait-analysis [28,29], or 3D gait-analysis was included, but focus was on comparing AFOs with functional electrical stimulation [30–33], instead of focussing on the effects of timing of the AFO-provision itself. Another strength of our study is that we included the subjects in an early phase after stroke. Thereby, the study conditions match with the situation in which clinicians often consider AFOs.

The major study-limitation is the small sample size, probably underpowering the results. The sample size was limited further at T1 since not all subjects were able to perform this measurement. We did not include subjects that dropped-out after T1 or T2 in the original analysis. Post-hoc intention-to-treat analysis including these subjects showed that this did not affect results. Other study-limitations relate to the longitudinal study-design. We measured in a period in which large functional improvements after stroke are seen [22], which means that it was inevitable that some measurement conditions changed during the study. Although we tried to limit variation as much as possible, changes in walking aids and shoes between measurements could have affected our results. Furthermore, it was not possible to blind subjects and assessor for AFO-use.

In conclusion, the results of our study indicate that AFO-use, both early and delayed after stroke, does not influence frontal pelvis and hip, and sagittal hip and knee movements of the affected limb after 26 weeks, despite that the AFO properly corrected drop-foot. Therefore, AFOs should be provided to improve drop-foot, but not with the intention to prevent or affect development of compensatory movement patterns around pelvis and hip after stroke.

Contributors

CN: Conception and design of the study, acquisition of data, analysis and interpretation of the data, drafting, revising and final approving the article. JvdP: statistical 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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