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Early or delayed provision of an ankle-foot orthosis in patients with acute and subacute stroke: a randomized controlled trial

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Abstract

Objective: (1) To study the effects of providing ankle-foot orthoses in subjects with (sub)acute stroke; and (2) to study whether the point in time at which an ankle-foot orthosis is provided post-stroke (early or delayed) influences these effects.
Design: Randomized controlled trial.
Setting: Rehabilitation centre.
Subjects: Unilateral hemiparetic stroke subjects with indication for use of an ankle-foot orthosis and maximal six weeks post-stroke.
Interventions: Subjects were randomly assigned to: early provision (at inclusion; Week 1) or delayed provision (eight weeks later; Week 9).
Outcome measures: 10-metre walk test, 6-minute walk test, Timed Up and Go Test, stairs test, Functional Ambulation Categories, Berg Balance Scale, Rivermead Mobility Index and Barthel Index; assessed in Weeks 1, 3, 9 and 11.
Results: A total of 33 subjects were randomized (16 early, 17 delayed). Positive effects of ankle-foot orthoses were found two weeks after provision, both when provided early (significant effects on all outcomes) or delayed (Berg Balance Scale $p = 0.011$, Functional Ambulation Categories $p = 0.008$, 6-minute walk test $p = 0.005$, Timed Up and Go Test $p = 0.028$). Comparing effects after early and delayed provision showed that early provision resulted in increased levels of improvement on Berg Balance Scale (+5.1 points, $p = 0.002$), Barthel Index (+1.9 points, $p = 0.002$) and non-significant improvements on 10-metre walk test (+0.14 m/s, $p = 0.093$) and Timed Up and Go Test (–5.4 seconds, $p = 0.087$), compared with delayed provision.

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Conclusions: We found positive effects of providing ankle-foot orthoses in (sub)acute stroke subjects that had not used these orthoses before.

Keywords
Ankle-foot orthosis, stroke rehabilitation, functional outcome, timing of provision, randomized controlled trial

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Introduction

Ankle-foot orthoses are often applied during stroke rehabilitation and may provide mediolateral stability in stance, facilitate toe-clearance in swing, and promote heel strike.[1] Despite the frequent application of ankle-foot orthoses, there is little scientific evidence available to guide provision of ankle-foot orthoses early after stroke. The majority of trials studying the effects of ankle-foot orthoses included subjects that were already using their orthosis in everyday life and subjects were measured while walking both with and without the orthosis.[2–7] In this situation, the effect of removing the orthosis is tested, rather than effects of providing ankle-foot orthoses, which does not completely reflect the kind of knowledge clinicians need. To our knowledge, no previous studies looked at the effects of the actual provision of ankle-foot orthoses itself on functional outcome measures early after stroke.

Another limitation in the current body of evidence with respect to clinical practice is that 'a misalignment between timing of RCTs [randomized controlled trials] and the real-world delivery of stroke rehabilitation may be an important aspect of the evidence base that limits its translation to clinical practice'.[8] Many previously conducted studies included chronic stroke patients,[9] which does not correspond to daily practice where ankle-foot orthoses are often prescribed in the (sub)acute phase.

Another important consideration in studying the literature of use of ankle-foot orthoses after stroke is that effects in more severely affected subjects are not well studied, since most studies included subjects that were able to walk independently with or without walking aid.[9] Only four studies included subjects with no walking ability in everyday life.[3,10–12]

The aforementioned considerations show that there is a lack of studies examining the effects of the provision of ankle-foot orthoses and the timing of this provision to patients in their early rehabilitation post-stroke.[9] Therefore, we conducted an explorative randomized controlled trial to study the effects of providing ankle-foot orthoses on two different time points post-stroke. Both patients with and without independent walking ability were included. The primary aim of the current article was to investigate the effects of the actual provision of ankle-foot orthoses on balance, walking, and activities of daily life. The secondary aim was to study whether the point in time (early or delayed) at which the ankle-foot orthosis was provided post-stroke influenced these effects. We hypothesised that early provision is more beneficial.

Methods

We designed a single centre, randomized, controlled, parallel group study. The study was approved by the Medical Ethical Committee Twente and registered in the 'Netherlands Trial Register', number NTR1930. All subjects provided written informed consent. Subjects were allocated by an independent person, using stratified block randomization with sealed envelopes (strata based on Functional Ambulation Categories (FAC) levels[13] 0–2 vs. 3–5, envelopes filled in blocks of four with a ratio 1:1), to either: (1) ankle-foot orthosis provision at inclusion in the study, in study Week 1 (early group); or (2) delayed ankle-foot orthosis provision after eight weeks, in study Week 9 (delayed group). Effects were assessed

two weeks after provision, in study Weeks 3 and 11 for the early and delayed group, respectively.

Baseline measurements were performed without orthosis in Week 1 for the early group (Figure 1). Subjects were provided with the ankle-foot orthosis after these measurements and effect of the provision was studied two weeks later, in Week 3. Natural recovery is expected in this period and this will interfere with the effects of orthosis provision. Therefore, the delayed group (not using an ankle-foot orthosis in this period) was also measured in Weeks 1 and 3 and can serve as a control group in this period. In Week 9 the delayed group was measured without ankle-foot orthosis and subjects were provided with the orthosis after the measurements. Two weeks later, in Week 11, the effect of the provision was measured. In Weeks 9 and 11 the early group (already provided with an ankle-foot orthosis) was also measured as a reference. Besides the different timing of the provision of the orthosis, all subjects received usual care from experienced physiotherapists according to the Dutch guidelines for physiotherapy after stroke.[14]

Subjects

Subjects were recruited by the main researcher between December 2009 and March 2014 from the Roessingh, Centre for Rehabilitation in Enschede, the Netherlands. Inclusion criteria were: (1) unilateral ischemic or haemorrhagic 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 inpatient rehabilitation care at inclusion; (5) able to follow simple verbal instructions; and (6) indication for use of an ankle-foot orthosis (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. Exclusion criteria were: (1) suffering from severe comprehensive aphasia or neglect; and (2) complicated medical history, such as cardiac, pulmonary, or orthopaedic disorders, that could interfere with testing.

Ankle-foot orthosis protocol

No standard practice for providing ankle-foot orthoses regarding timing and type of orthosis is available in the Netherlands. Subjects were provided with one of three commonly used types of off-the-shelf, non-articulated, posterior leaf design, polyethylene, or polypropylene ankle-foot orthoses: flexible, semi-rigid, or rigid (Basko Healthcare, Zaandam, the Netherlands) (Figure 2, available online). All orthoses included a proximal calf strap. Fitting was performed by a licensed orthotist. Type of orthosis was chosen in Week 1 (early group) or Week 9 (delayed group) according to a custom-developed protocol based on the prerequisites of gait,[15] determining whether the main walking problems were related to stability in stance, foot clearance in swing, and/or prepositioning at heel strike (see Figure 3, available online). In all subjects the effect of the prescribed ankle-foot orthosis was verified and confirmed by the responsible physician.

Outcome measures

At inclusion, basic demographic data were recorded and subjects completed the Mini-Mental State Examination,[16] Erasmus MC modifications to the Nottingham Sensory Assessment, lower-limb part,[17] and the Motricity Index, lower-limb part.[18]

The primary outcome measure was comfortable walking speed, assessed with the 10-metre walk test.[19] Secondary, balance was assessed using the Berg Balance Scale,[20] walking ability with the 6-minute walk test,[21] functional mobility with the Timed Up and Go Test[22] and Stairs Test,[5] and independence of walking with the FAC.[13] The Rivermead Mobility Index[23] and Barthel Index[24] were used to assess mobility during activities of daily life.

All tests were administrated by trained research physiotherapists and measurements were performed at the rehabilitation centre. Blinding of the assessor to use of the orthosis or early or delayed provision was not possible. For all walk tests, subjects were allowed to use their usual assistive device (cane or quad cane) and actual use was recorded. Changes in assistive devices between the

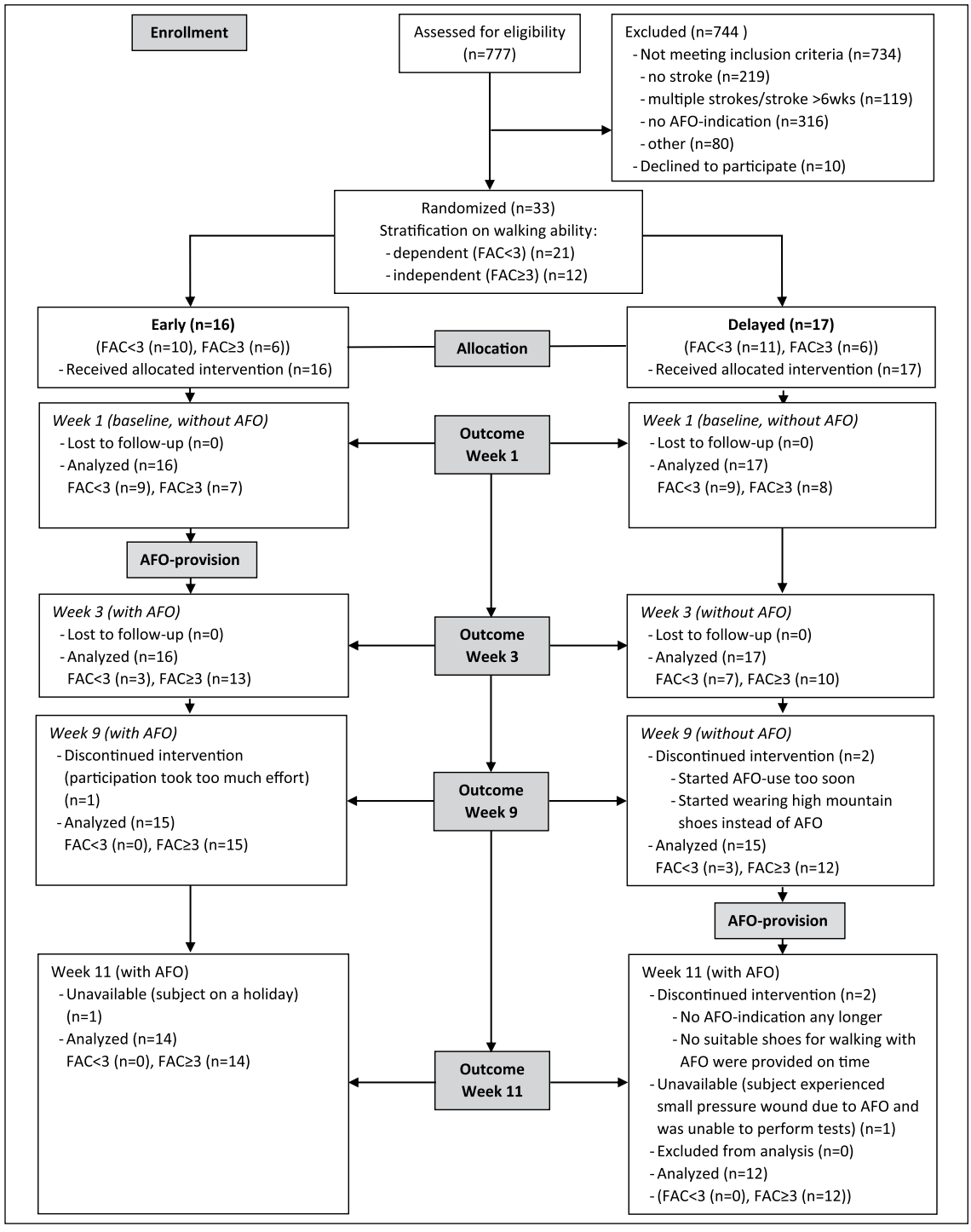

Figure 1. Flowchart.
AFO: ankle-foot orthosis; FAC: Functional Ambulation Categories.

measurements were allowed. All functional tests that included walking were only performed in case subjects could walk without physical support (minimum FAC level 3 required) at the time of the measurement.

Data analysis

A power calculation was not performed as data of previous studies measuring timing effects of providing ankle-foot orthoses early or later after stroke were not available. IBM SPSS Statistics version 19 (IBM SPSS Statistics, Chicago, USA) was used for data-analysis. Continuous data are presented as mean (standard deviation (SD)) or median (interquartile ranges (IQR)), as appropriate. The level of significance for all analyses was set at $p < 0.05$. In case walk tests could not be performed because FAC <3, the 10-metre walk test and 6-minute walk test were set at 0.0 m/s and 0 m, respectively, while the Timed Up and Go Test and Stairs Test were treated as missing values since using 0 seconds for these outcome measures would mean an infinite fast performance of the test. In order to answer the primary research question, the effects of ankle-foot orthoses were determined comparing differences of Weeks 1–3 for the early group and Weeks 9–11 for the delayed group using the Wilcoxon signed rank test. Since natural recovery is expected during the period of measurements (especially in Weeks 1–3), the effect of the orthosis provision is expected to be mixed with effects of natural recovery. Therefore, the Wilcoxon signed rank test was also used to compare scores for Weeks 1–3 in the delayed group (indicating natural recovery). The Wilcoxon rank sum test was used in Weeks 1–3 to compare scores of the early (orthosis-effect and natural recovery) and delayed group (only natural recovery). For Weeks 9–11 an additional Wilcoxon signed rank test was performed to indicate progress in the early group with ankle-foot orthosis. The Wilcoxon rank sum test was not performed, as in this period the early group was already using an ankle-foot orthosis for an extended period of time. The secondary research question was whether or not the point in time at which an orthosis is provided (early or delayed) influences the effects of provision. We used analysis of covariance (ANCOVA) and analysed whether the effects of providing an orthosis are different for the early and delayed group. This implies looking at the outcomes at Week 3 for the early group and Week 11 for the delayed group (measurement with orthosis). The independent variables were group assignment (early or delayed) and values of the outcome of interest at Weeks 1 and 9 for the early and delayed group, respectively (measurement without orthosis). To check whether the assumptions for ANCOVA analysis were fulfilled, we checked the distribution of the regression standardised residuals.

Results

Baseline characteristics

In total 33 subjects were included; 16 in the early group, 17 in the delayed group. There were no significant differences at baseline between both groups (Table 1). Figure 1 details the participant flow through the study. Five subjects dropped-out (one early, four delayed) and data of two additional subjects (one early, one delayed) were unavailable in Week 11.

Effects of ankle-foot orthosis provision

Mean time since stroke (SD) at provision of the ankle-foot orthosis was 32.0 days (6.2) for the early group ($N = 16$) and 88.1 days (6.1) for the delayed group ($N = 13$). Table 2 shows the median scores of both groups for Weeks 1 and 9, and the improvements after providing ankle-foot orthoses in the early (Weeks 1–3) and delayed group (Weeks 9–11). Furthermore, effects of only natural recovery are shown for the delayed group (improvement Weeks 1–3), as are the results of Weeks 9–11 for the early group. In the early group, median improvements after orthosis provision from Week 1 to Week 3 were significant for all outcome measures (all $p \leqslant 0.028$). In the same period the delayed group (not using an orthosis) also showed significant improvements on all outcome measures ($p \leqslant 0.037$), except for the Stair Test ($p = 0.068$).

Table 1. Subject characteristics.

		Total ($N=33$)	Early ($N=16$)	Delayed ($N=17$)
Sex (male/female)		20/13	10/6	10/7
Age (years, mean ±SD)		57.2 (9.2)	56.9 (9.6)	57.5 (9.1)
Time since stroke at Week 1 (days, mean ±SD)		31.4 (6.3)	32.0 (6.2)	30.8 (6.5)
Affected body side (left/right)		16/17	8/8	8/9
Type of stroke (ischemic/haemorrhagic)		27/6	14/2	13/4
Type of ankle-foot orthosis (flexible/semi-rigid/rigid/no orthosis)		27/0/3/3	14/0/2/0	13/0/1/3
Sensation[a]	Tactile (normal/impaired/absent)	26/4/3	13/1/2	13/3/1
	Propriosepsis (normal/impaired/absent)	26/6/1	13/2/1	13/4/0
Mini-Mental State Examination (mean ±SD)		25.5 (4.1)	25.4 (4.5)	25.5 (3.8)
Motricity Index, lower limb (mean ±SD)		30.3 (20.0)	32.0 (17.8)	28.8 (22.3)

[a]Tested with Erasmus MC modifications to the Nottingham Sensory Assessment, lower limb part.

However, comparing the median improvements of the early group (using the orthosis) and the delayed group (only natural recovery) showed that improvements were numerically larger in the early group, except for FAC and Rivermead Mobility Index. The Berg Balance Scale (+8.5 points, $p=0.017$) and the 10-metre walk test (+0.23 m/s, $p=0.025$) showed statistically significant larger median improvements in the early group, the 6-minute walk test showed non-significant improvements (+62.5 m, $p=0.076$). Provision of the orthosis in Week 9 in the delayed group resulted in median improvements on all outcome measures, except for Rivermead Mobility Index and Barthel Index. The Berg Balance Scale ($p=0.011$), FAC ($p=0.008$), 6-minute walk test ($p=0.005$) and Timed Up and Go Test ($p=0.028$) increased statistically significantly. The Rivermead Mobility Index and Stairs Test showed non-significant improvements ($p=0.066$ and $p=0.075$, respectively). As a reference, median improvements from Weeks 9 to 11 of the early group (already using an orthosis) are also presented, showing only a significant median improvement of the Rivermead Mobility Index of 0.5 points ($p=0.016$).

Effect of early or delayed provision

Table 3 shows the results of the ANCOVA comparing the effects of early or delayed provision of the ankle-foot orthosis, thereby correcting for differences in Week 1 and Week 9 scores, respectively, at the time the orthosis was provided. Adding 'time after stroke' or 'time in the rehabilitation centre' as independent variables did not result in improvement of the model and therefore were left out. Except for FAC and Stairs Test, effects two weeks after provision were higher in the early group compared with the delayed group. Correcting for differences in baseline values at the two time points of provision of the orthosis, the early group improved 5.1 points more on the Berg Balance Scale ($p=0.002$) and 1.9 points more on the Barthel Index than the delayed group two weeks after provision ($p=0.002$). The 10-metre walk test and Timed Up and Go Test showed non-significant improvements of 0.14 m/s extra increase in walking speed ($p=0.093$) and 5.4 seconds faster performance ($p=0.087$), respectively, in the early group compared with the delayed group two weeks after provision.

Discussion

This study showed positive effects of providing ankle-foot orthoses on functional outcomes, whether provided early (on average 32.0 days (6.2) after stroke) or delayed by eight weeks in subjects that did not use an ankle-foot orthosis before. These positive effects were more pronounced in the early group, suggesting that providing ankle-foot orthoses early after stroke may be beneficial.

Our primary aim was to study the effects of the actual provision of ankle-foot orthoses early after

Table 2. Effect of providing ankle-foot orthoses comparing Weeks 1–3 and Weeks 9–11.

	Early						Delayed						Weeks 1–3 difference early – delayed[b]
	N	Week 1	Improvement Weeks 1–3 (without vs. with orthosis)[a]	*N*	Week 9	Improvement Weeks 9–11 (with vs. with orthosis)[a]	*N*	Week 1	Improvement Weeks 1–3 (without vs. without orthosis)[a]	*N*	Week 9	Improvement Weeks 9–11 (without vs. with orthosis)[a]	
BBS	16	28.5	+11.5 (5.3; 17.8)*	14	49.5	0.0 (0.0; 1.3)	17	25.0	+3.0 (1.5; 11.5)*	12	46.5	+3.0 (0.0; 4.0)*	+8.5*
FAC	16	2.0	+1.0 (0.0; 1.0)*	14	4.0	0.0 (0.0; 0.0)	17	2.0	+1.0 (0.0; 1.0)*	12	4.0	+1.0 (0.0; 1.0)*	0.0
RMI	16	5.0	+2.0 (1.0; 3.8)*	14	12.0	+0.5 (0.0; 2.0)*	17	6.0	+2.0 (0.0; 4.0)*	12	12.0	0.0 (0.0; 1.0)	0.0
10MWT (m/s)[c]	16	0.00	+0.23 (0.08; 0.34)*	14	0.56	+0.01 (–0.02; 0.07)	17	0.00	0.00 (0.00; 0.18)*	12	0.36	+0.02 (–0.04; 0.18)	+0.23*
6MWT (m)[c]	16	0.0	+67.5 (7.0; 108.5)*	12	176.3	+6.5 (–5.5; 22.9)	17	0.0	+5.0 (0.0; 58.8)*	12	121.3	+38.0 (10.9; 60.5)*	+62.5
BI	16	12.0	+2.5 (1.0; 3.8)*	14	18.0	0.0 (0.0; 0.3)	17	12.0	+2.0 (0.0; 3.5)*	12	18.0	0.0 (0.0; 0.8)	+0.5
TUG (sec)[c]	7	23.8	–9.1 (–14.3; –3.1)*	14	25.2	–0.1 (–1.2; 1.4)	8	30.3	–5.6 (–16.9; –3.5)*	9	24.0	–3.8 (–5.9; –0.8)*	–3.5
ST (sec)[d]	6	85.9	–20.1 (–22.5; –8.6)*	12	53.0	–1.1 (–4.4; 4.2)	4	51.3	–14.9 (–31.3; –7.1)	6	45.8	–3.8 (–16.2; –0.1)	–5.2

*$p < 0.05$; Median scores and median improvements (interquartile range) are presented.

[a]Wilcoxon signed rank (within group).

[b]Wilcoxon rank sum test (between group).

[c]10MWT was set at 0.0 m/s, 6MWT set at 0 m and TUG was missing in case subjects scored FAC < 3. In the early group, this was the case in nine and three subjects in Weeks one and three, all subjects were able to perform the test in Weeks nine and eleven. For the delayed group this was the case in: nine, seven, and two subjects in Weeks one, three, and nine, respectively. All subjects were able to perform the test in Weeks eleven. In Weeks 9–11 6MWT was missing in two additional subjects (early) and TUG was missing in one additional subject (delayed).

[d]In the early group ten, six, two, and one subjects were not able to perform the ST in Weeks one, 3, 9, and 11, respectively. This was the case in thirteen, eight, five, and four subjects in the delayed group. In Weeks 9–11, the additional data of one subject was missing (delayed).

BBS: Berg Balance Scale; FAC: Functional Ambulation Categories; RMI: Rivermead Mobility Index; 10MWT: 10-metre walk test; 6MWT: 6-minute walk test; BI: Barthel Index; TUG: Timed Up and Go Test; ST: Stairs Test.

Note that negative results of TUG and ST indicate faster performance of the test.

Table 3. Analysis of covariance of the effects of providing ankle-foot orthoses comparing the early and delayed group.

	N	Difference	95% confidence interval for difference	
			Lower	Upper
BBS	28	–5.1*	–8.052	–2.134
FAC	28	0.1	–0.420	0.590
RMI	28	–0.9	–2.179	0.284
10MWT (m/s)	28	–0.14	–0.295	0.024
6MWT (m)	28	–30.4	–82.980	22.259
BI	28	–1.9*	–2.972	–0.760
TUG (sec)	16	5.4	–0.909	11.799
ST (sec)	12	–0.9	–9.592	7.806

*$p < 0.05$.

BBS: Berg Balance Scale; FAC: Functional Ambulation Categories; RMI: Rivermead Mobility Index; 10MWT: 10-metre walk test; 6MWT: 6-minute walk test; BI: Barthel Index; TUG: Timed Up and Go Test; ST: Stairs Test.

Note that for all outcome measures (except TUG and ST) negative results indicate that the early group improved more compared with the delayed group, two weeks after providing the orthosis. For TUG and ST, negative results indicate that the delayed group improved more compared with the early group, two weeks after providing the orthosis.

stroke. When orthoses were provided in Week 1 we found significant improvements on all outcome measures for the early group. In the same period, all but one (Stairs Test) outcome measures improved in the delayed group. This delayed group was not using an orthosis and therefore the improvements in this group are indicative for the natural recovery occurring after stroke and can be useful in the interpretation of the improvements in the early group. This is of importance, as the differences in the early group have a mixed origin: they are made up of both natural recovery and the effect of providing the orthosis. Comparing the median improvement of the early group with the delayed group at Weeks 1–3, we found that improvements in the Berg Balance Scale and the 10-metre walk test were significantly larger in the early group. On other outcomes, no significant differences were found in median improvement between the early and delayed group for Weeks 1–3. We believe that these results are indicative for the short-term effect of providing the ankle-foot orthosis in the early group.

When orthoses were provided to the delayed group in Week 9 and effects were measured in Week 11, we found significant improvements on the Berg Balance Scale, FAC, 6-minute walk test and Timed Up and Go Test. In the same period, the early group was already using an orthosis and showed only a significant improvement on the Rivermead Mobility Index. The early group cannot be compared with the delayed group, as indication for the amount of natural recovery in Weeks 9–11 since the early group was provided with the orthosis eight weeks earlier.

When looking at the magnitude of the effects, we found a striking improvement on walking speed of +0.23 m/s for provision in Weeks 1–3 for the early group. This improvement, which can be considered clinically relevant,[25–27] is higher compared with a previous review reporting improvements of around 0.06 m/s (95% CI 0.03–0.08) for walking speed.[9] The difference in effect could not be explained by the fact that we also included subjects without independent walking ability, as post-hoc analysis including only patients with independent walking ability in Weeks 1–3 (early $N=7$; delayed $N=8$) resulted in median improvements of +0.28 m/s (early; $p = 0.018$) and +0.06 m/s (delayed; $p = 0.123$). Furthermore, the difference could not be explained by the short stroke onset time in our study (a phase after stroke in which improvements are known to be highest[28]) or our measurement protocol that included a two-week interval between the measurements (in which natural recovery may take place). This can be concluded from the fact that the large improvements on walking speed were only found in the early group that was provided with an orthosis, and not in the delayed group. The delayed group can serve as a control group as they had comparable stroke onset time and measurement protocol. Apparently, including subjects with FAC level <3 and the early onset time after stroke in our study cannot explain our results for walking speed. Therefore, we assume that the effects can be contributed to the early provision of the ankle-foot orthosis, suggesting that the positive results of ankle-foot

orthoses on walking speed in chronic stroke reported previously may be more pronounced when the orthosis is provided early after stroke. Another striking improvement of providing the orthosis in Weeks 1–3 between the early and delayed group was the result of the Berg Balance Scale (+8.5 points, $p = 0.017$). This improvement is clinically relevant[29,30] and more pronounced than improvements of around 1–2 points previously reported.[6,31] Balance performance of the included subjects in the two previous studies was higher compared with our study. Ceiling-effects are well known for the Berg Balance Scale[32] and may explain why smaller effects were reported in those studies.

Our secondary aim was to study whether or not the point in time at which an orthosis is provided influences the effects of the provision. The ANCOVA showed a significantly higher improvement for early provision on the Berg Balance Scale and Barthel Index (extra median improvement of +5.1 and +1.9 points, respectively). These results are around the clinical meaningful changes reported for the Berg Balance Scale[30] and Barthel Index.[33] In addition, we found a trend in improvements on the 10-metre walk test and Timed Up and Go Test, indicating that early provision may be beneficial on aspects of balance, activities of daily living, and walking ability.

Our finding that the effects of ankle-foot orthoses may be more pronounced when provided early after stroke adds new insights to the available literature, as hardly any knowledge about the effects of the timing of providing orthoses after stroke is available. Only Wang et al.[31] studied effects of ankle-foot orthoses in stroke subjects with hemiparesis of different durations before. They found that the orthosis improved symmetry in quiet standing, dynamic standing balance, speed, and cadence in subjects less than six months after stroke, whereas only weak effects in subjects over 12 months post-stroke were found.

An important strength of this study is that this is the first study that takes timing of providing ankle-foot orthoses after stroke into account. Furthermore, the intervention is studied in a time frame and subject population that reflects clinical practice. We recruited subjects early after stroke and without experience in walking with an orthosis. The relation to the clinical practice is further strengthened since we also included subjects without independent walking ability. The majority of the subjects received a flexible ankle-foot orthosis because of problems with drop-foot. This type of walking problem is often seen in stroke rehabilitation. Therefore, we think that our results are representative for daily clinical practice.

Five subjects dropped-out in the study (one early, four delayed) for various reasons (see Figure 1). We have no reasons to believe that drop-out rates were related to the intervention. Since data of previous studies measuring timing effects were not available, no valid power calculations could be performed to determine the sample size for this explorative randomized controlled trial. Together with a small sample size, this is a limitation of our study. Despite the lack of a power calculation and the small sample size of our study, we are convinced that our sample size was sufficient since we were able to detect statistically significant effects. Another limitation is that it was not possible to blind subjects and assessors for early or delayed provision of the orthosis, which is a potential risk of bias.

This report focused on the effects of providing ankle-foot orthoses and whether or not early or delayed provision influences these effects. Functional outcomes were included and effects were studied two weeks after provision. Effects on the long-term follow-up need further study. A possible long-term adverse effect of early provision often mentioned by therapists is that use of an ankle-foot orthosis would enhance disuse of the tibialis anterior muscle.[34] However, one might also speculate about positive effects of early use of an orthosis, as the ankle-foot orthosis is reported to limit foot-drop in the distal segment, which may diminish the need of developing compensatory movements in more proximal segments. Therefore, future analysis of kinematics and muscle activation patterns is necessary to give insight in these effects of ankle-foot orthoses after stroke. Whether or not the early provision leads to benefits, like higher levels of mobility in an earlier stage of the rehabilitation or shortening of length of stay in the rehabilitation centre, was not studied in this current research and should be investigated in a next study.

Clinical message

- There are considerable positive effects of providing an ankle-foot orthosis on balance, walking ability, and activities of daily life in subjects with (sub)acute stroke that have not used an orthosis before.
- The positive effects of providing an ankle-foot orthosis are more pronounced when the orthosis is provided early (on average 32.0 days (6.2)) after stroke.

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Contributors

CN: Conception and design, measurements, analysis, interpretation of the data, drafting, and final approving the article. JB, HH, JR: Conception and design, interpretation of the data, revising, and final approving the article. JvP: Analysis, interpretation of the data, revising, and final approval of the article.

Conflict of interest

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The ankle-foot orthoses used in this study were provided by Basko Healthcare, Zaandam, the Netherlands. Basko was not involved in designing, collecting data, or the statistical analysis of study. In addition, they had no role in writing the article and the decision to submit the article for publication.

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