Effect of Providing Ankle-Foot Orthoses in Patients with Acute and Subacute Stroke: A Randomized Controlled Trial

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Abstract Despite frequent application of ankle-foot orthoses (AFOs), little scientific evidence is available to guide AFO-provision early after stroke. A randomized controlled trial was conducted to study the effects of AFO-provision in (sub-) acute stroke patients. Primary aim: to study effects of the actual provision of AFOs on functional outcomes. Secondary aim: to study whether the point in time at which an AFO is provided (early (week 1) or delayed (week 9)), influences these effects. Thirty-three subjects were included and walking speed, balance (Berg Balance Scale, BBS) and independence of walking (Functional Ambulation Categories, FAC) were measured. Positive effects of AFO-provision were found two weeks after provision, both when provided early (significant effects on all outcome measures) or late (BBS $p = 0.011$, FAC $p = 0.008$). Comparing the early and delayed group showed that early provision resulted in extra improvements on BBS (+5.1 points, $p = 0.002$) compared to late provision.

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1 Introduction

Ankle-Foot Orthoses (AFOs) are often applied during stroke-rehabilitation [1]. There are several limitations in the current body of evidence of AFO-use in stroke with respect to clinical practice. The majority of trials studying the effects of AFOs included subjects that were already using an AFO in their everyday life [2, 3]. Furthermore, many previously conducted studies included chronic stroke patients [4] and most of them were able to walk independently with or without walking aids [4]. These studies do not completely reflect the kind of knowledge clinicians need, as the effect of removing the AFO is measured when habitual AFO-walkers are tested with and without AFO, rather than the effect of providing the AFO. Furthermore, effects are tested in a population that does not correspond to daily clinical practice were AFOs are often prescribed in the (sub-) acute phase to patients that are not able to walk independently. There is a lack of studies examining the effects of the provision of AFOs and the timing of this provision to patients in the early rehabilitation post-stroke. Therefore, we conducted an explorative randomized controlled trial to study the effects of providing AFOs on two different moments post-stroke. The primary aim was to investigate the effects of the actual provision of AFOs. The secondary aim was to study whether the point in time (early or delayed) at which the AFO was provided post-stroke influenced these effects. This paper will focus on the effects on functional outcome measures. Walking speed, balance and independence of walking were measured as these aspects are important in the rehabilitation after stroke and often reported to be affected by AFO-use [4].

2 Materials and Methods

We designed a single center, randomized, controlled, parallel group study. The study was approved by the local Medical Ethical Committee. Subjects were randomized to either (1) AFO-provision at inclusion of the study (in study week 1; early group); or (2) delayed AFO-provision after eight weeks (in study week 9; delayed group). Subjects were recruited from the Roessingh, Centre for Rehabilitation, Enschede, the Netherlands. Inclusion criteria were: unilateral ischemic or hemorrhagic stroke leading to hemiparesis; at least 18 years of age; maximal six weeks post-stroke; receiving in-patient rehabilitation care at inclusion; able to follow simple verbal instructions; and indication for AFO-use (problems with stability in stance, foot clearance and/or prepositioning) determined by the treating rehabilitation physician and physiotherapist. Exclusion criteria were: suffering from severe comprehensive aphasia or neglect; complicating medical history that could interfere with testing.

Subjects were provided with one of three types of off-the-shelf, non-articulated, posterior leaf design, polyethylene or polypropylene AFOs. After provision AFOs were used all day with rest periods during the night. Baseline measurements were

performed without AFO in week 1 for the early group. These subjects were provided with the AFO and effects of AFO-provision were assessed two weeks later, in week 3. Natural recovery is expected in this period after stroke and therefore the delayed group was also measured in week 1 and 3 to serve as a control group. In week 9 the delayed group was measured without AFO and these subjects were provided with the AFO after the measurements. In week 11 effects of AFO-provision were measured. The early group was also measured in week 9 and 11 as a reference. Besides the AFO-intervention all subjects received usual care from experienced physiotherapists according to the Dutch guidelines for physiotherapy after stroke [5].

Basic demographic data were recorded at inclusion. The primary outcome measure was comfortable walking speed, assessed with the 10-Meter Walk Test (10MWT) [6]. Secondary, balance and independence of walking were assessed using the Berg Balance Scale (BBS) [7] and Functional Ambulation Categories (FAC) [8], respectively. The 10MWT was only performed in case subjects could walk without physical support, otherwise 0.0 m/s was set.

The level of significance was set at $p < 0.05$ for all analyses. The Wilcoxon signed rank tests and Wilcoxon rank sum test were used to compare scores within groups (week 1−3 and week 9−11) and between groups (early and delayed week 1−3), respectively. Analysis of Covariance was used to analyze whether effects of AFO-provision were different for the early and delayed group, thereby correcting for differences in scores at the time the AFO was provided.

3 Results

Thirty-three subjects were included (16 early, 17 delayed) and five subjects dropped out (one early, four delayed). Inclusion was on average 31.4 days (6.3) after stroke. There were no significant differences at baseline between groups.

Table 1 shows median scores of both groups for week 1 and 9 and the improvements after AFO-provision in the early (week 1−3) and delayed group (week 9−11). Furthermore, effects of only natural recovery are shown for the delayed group (week 1−3), as are the results of week 9−11 for the early group. Significant improvements were found for all outcome measures in week 1−3, both in the early and delayed group. Comparing the median improvements of both groups showed that improvements in the early group were statistically significant larger for 10MWT and BBS, compared to the delayed group. AFO-provision in week 9 in the delayed group resulted in statistically significant median improvements on BBS and FAC. As a reference, the early group showed no significant improvements in this period.

Comparing effects of early and delayed provision showed that effects two weeks after provision were higher in the early group compared to the late group (results not shown). Subjects in the early group improved 5.1 points more on the BBS ($p = 0.002$) than the delayed group two weeks after AFO-provision. The 10MWT

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

	Early						Delayed						
	N	Wk 1	Improvement wk 1–3 (without vs with AFO)[1]	N	Wk 9	Improvement wk 9–11 (with vs with AFO)[1]	N	Wk 1	Improvement wk 1–3 (without vs without AFO)[1]	N	Wk 9	Improvement wk 9–11 (without vs with AFO)[1]	Wk 1–3 difference early–late[2]
10MWT	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*
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

*$p < 0.05$; Median scores and median improvements (interquartile range) are presented; [1]Wilcoxon signed rank (within group); [2]Wilcoxon rank sum test (between group) Abbreviations: AFO: Ankle-Foot Orthosis; 10MWT: 10-Meter Walk Test; BBS: Berg Balance Scale; FAC: Functional Ambulation Categories

showed borderline significant results of 0.14 m/s ($p = 0.093$) in the early group compared to the delayed group two weeks after provision. No significant effects were found for FAC.

4 Discussion and Conclusion

This is the first study that takes timing of AFO-provision into account. We studied this intervention in a time frame and subject population that reflects clinical practice. We found positive effects of AFO-provision on functional outcomes, both when provided early (on average 4.5 weeks after stroke) or delayed with eight weeks in subjects that did not use an AFO before. The positive effects were more pronounced in the early group, suggesting that AFOs should be provided early after stroke. Our findings add new insights to the available literature, as hardly any knowledge about the effects of the timing of AFO-provision after stroke is available. More research is needed on effects on the long-term, including spatiotemporal and kinematic effects on gait pattern.

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