Ankle-Foot Orthoses in the Rehabilitation After Stroke: Results of a Randomized Controlled Trial

Corien D. M. Nikamp, Johan S. Rietman, Erik C. Prinsen, Hermie J. Hermens, and Jaap H. Buurke

Abstract This paper provides an overview of the results of the EVOLUTIONS-trial, in which effects of providing ankle-foot orthoses on two different points in time in the rehabilitation after stroke were studied. Results showed functional improvements over time, while at the same time no changes in kinematics and muscle activity of the affected lower limb were found over a period of 26 weeks. Based on these results, compensation strategies of the unaffected lower limb are thought to play an important role in the rehabilitation after stroke.

1 Introduction

Walking function is often impaired after stroke. In order to improve walking, Ankle-Foot Orthoses (AFOs) are frequently prescribed. When looking into the available evidence of AFO-use after stroke, the majority of studies compared the effects of AFOs in short-term designs, in patients who were able to walk independently, who used AFOs already in daily life and were in the chronic state after stroke. These conditions do not match the conditions of stroke patients admitted in rehabilitation centers for which AFO-prescription are considered. As a result, there was insufficient evidence available to inform clinicians about whether or not to prescribe AFOs early or later after stroke, and about effects of long-term AFO-use. Therefore, the EVOLUTIONS-trial was conducted, in which the effects of providing AFOs on

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C. D. M. Nikamp (✉) · J. S. Rietman · E. C. Prinsen · H. J. Hermens · J. H. Buurke
Roessingh Research and Development, Enschede, The Netherlands
e-mail: c.nikamp@rrd.nl

University of Twente, Enschede, The Netherlands

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two different time points in the sub-acute rehabilitation post stroke were studied. Individual publications based on the results of this trial are already available and studied, amongst others, the effects on functional outcome measures [1], kinematics [2] and activity of the Tibialis Anterior (TA) muscle [3]. The aim of the current paper is to combine these results and state broad conclusions regarding the effect of AFO-provision on overall improvement after stroke.

2 Material and Methods

2.1 Study Design

We conducted a single center, randomized, controlled, parallel group study. The study was approved by the Medical Ethical Committee Twente and registered in the Dutch Trial register as NL1820. Subjects with and without independent walking ability were equally randomized into either AFO-provision at inclusion, study week 1 (early group), or AFO-provision eight weeks later, in study week 9 (delayed group).

2.2 Participants

Subjects were recruited from the Roessingh, Center for Rehabilitation in Enschede, The Netherlands. Inclusion criteria were: unilateral ischemic or hemorrhagic stroke leading to hemiparesis; minimal 18 years; maximal six weeks post-stroke; receiving inpatient rehabilitation care at inclusion; able to follow simple verbal instructions; indication for AFO-use determined by the treating rehabilitation physician and physiotherapist. Exclusion criteria were severe comprehensive aphasia, neglect or cardiac, pulmonary or orthopedic disorders that could interfere with gait.

2.3 Study Procedure

Longitudinal measurements were performed until 26 weeks after inclusion. Clinical tests related to balance, walking and activities of daily living were studied up to 17 weeks with biweekly intervals and a follow-up measurement at 26 weeks. 3D gait analyses measurements (using Vicon) including EMG-measurements were performed four times in the period of 26 weeks (in week 1, 9, 17 and 26). For more details and a full description of the study procedures, we would like to refer to the available papers [1–3].

Fig. 1 Three types of non-articulated AFOs used in the study

2.4 Intervention

Subjects were provided with one of three commonly used types of off-the-shelf, non-articulated, posterior leaf design, polyethylene or polypropylene AFOs. The types included flexible, semi-rigid or rigid designs (Basko Healthcare, Zaandam, The Netherlands), as shown in Fig. 1. Besides AFO-provision in week 1 (early group) or week 9 (delayed group), all subjects received usual care from experienced physiotherapists.

2.5 Outcome Measures

Clinical tests included walking speed (10 m walk test) and distance (6 min walk test), balance (Berg Balance Scale), functional mobility (Timed Up and Go Test, Stairs Test), independence of walking (Functional Ambulation Category) and activities of daily life (Rivermead Mobility Index and Barthel Index). 3D gait analysis included frontal and sagittal kinematics of the affected lower limb; spatiotemporal parameters and muscle activity patterns of amongst others the affected TA muscle.

2.6 Data Analysis

Independent group analysis were used to compare results after 26 weeks between the early and delayed group. Generalized Estimating Equation analyses and mixed model repeated measures analysis were performed to compare group by time interactions.

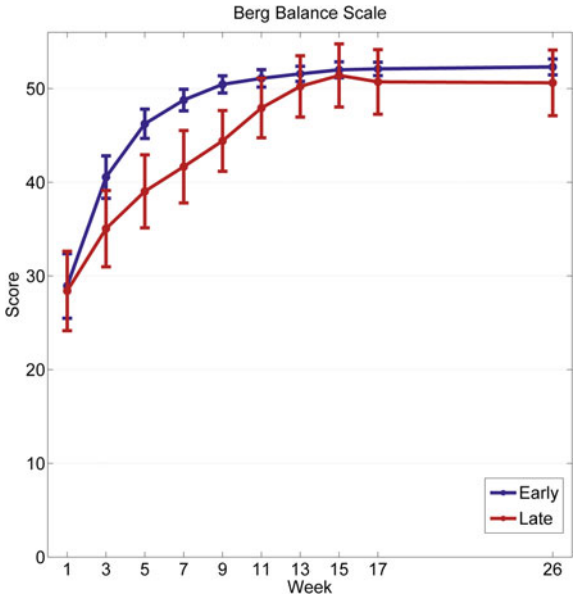

Fig. 2 Example of clinical test for the early (blue) and delayed (red) group. Mean (SE) score of the Berg Balance Scale is shown [1]

3 Results

Thirty-three subjects (16 early, 17 delayed) were included in the study of which six dropped out. Results of clinical tests showed that all subjects improved over time, see Fig. 2 for an example. The early group showed better outcomes on most tests in the first 11–13 weeks compared to the delayed group, but after 26 weeks no significant differences were found between both groups. Gait analysis showed that AFOs improved drop-foot during swing. Early or delayed AFO-provision did not influence pelvis, hip or knee kinematics during the 26 weeks. In addition, 26-weeks of AFO-use did not affect TA muscle activity and no differences with respect to TA muscle activity were found between both groups.

4 Discussion

We found no changes in kinematics and TA muscle activity of the affected lower limb over a period of 26 weeks after stroke. At the same time, subjects showed improvements on a functional level and early AFO-provision increased these improvements. This provokes discussion about how recovery after stroke is achieved. Behavioral restitution and compensation need to be distinguished in this discussion [4]. Behavioral restitution is defined as “return toward more normal patterns of motor control with the impaired effector” (for example the impaired ankle) and reflects the process

towards "true recovery". Compensation is described as "a patient's ability to accomplish a goal through substitution with a new approach, rather than using normal pre-stroke behavior." This includes intact muscles of the affected limb, but also the unaffected limb to accomplish the goal.

We found functional improvements over time, measured with clinical scales. However, these scales do not differentiate behavioral restitution from compensation. In our study, EMG and kinematic outcome measures were obtained simultaneously. These outcome measures, together with kinetic measures, are currently considered as the best way to differentiate behavioral restitution from compensation. Kinematics of the affected leg, together with affected TA EMGs did not change over time, while subjects functionally improved. Based on these results, compensation appears to be an important factor in stroke rehabilitation. This highlights the need for further research of the contribution of the unaffected lower limb in the rehabilitation after stroke. Changes in unaffected lower limb kinematics and changes in spatiotemporal parameters need further study.

5 Conclusion

Early AFO-use is expected to result in higher functional levels earlier on in the rehabilitation, but does not lead to higher functional levels after 26 weeks. The functional improvements over time were found, without changes in affected lower limb kinematics and TA EMG. Based on these results, compensation mechanisms, including the contribution of the unaffected lower limb, are thought to be important in the rehabilitation after stroke. This highlights the need for further research into the role of the unaffected lower limb in the rehabilitation after stroke.

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