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REVIEW ARTICLE (META-ANALYSIS)

Effects of an Ankle-Foot Orthosis on Balance and Walking After Stroke: A Systematic Review and Pooled Meta-Analysis

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Abstract

Objective: To determine the effectiveness of an ankle-foot orthosis (AFO) on mobility, walking, and balance in people with stroke.

Data Sources: The following databases were searched from inception to November 2011: Cochrane Stroke, Movement Disorders and Injuries Groups, MEDLINE, Embase, CINAHL, AMED, PsycINFO, and the Physiotherapy Evidence Database. Previous reviews, reference lists, and citation tracking of the selected articles were screened, and the authors of selected trials were contacted for any further unpublished data.

Study Selection: Randomized controlled trials of AFOs in people with stroke, which measured balance, walking impairments, or mobility and were reported in English, were selected. Then we independently identified trials, extracted data, and assessed trial quality.

Data Extraction: Trials with a low risk of selection, performance, and attrition bias were selected for analysis. Information on the trial design, population recruited, intervention delivered, outcomes measured, and the mean ± SD values for the treatment and control groups were extracted.

Data Synthesis: Continuous outcomes were combined using weighted or standardized mean differences with 95% confidence intervals and a fixed-effect model. Thirteen trials with 334 participants were selected. The effect of an AFO on walking activity ($P=.000-.001$), walking impairment ($P=.02$), and balance (weight distribution) ($P=.003$) was significant and beneficial. The effect on postural sway ($P=.10$) and timed mobility tests ($P=.07-.09$) was nonsignificant, and the effect on functional balance was mixed. The selected trials were all crossover trials of the immediate effects; long-term effects are unexplored.

Conclusions: An AFO can improve walking and balance after stroke, but only the immediate effects have been examined. The effects and acceptability of long-term usage need to be evaluated.

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The mobility of many stroke survivors is limited,[1] and most identify walking as a top priority for rehabilitation.[2] One way to manage walking difficulties is with a foot-drop splint (or ankle-foot orthosis [AFO]), which aims to stabilize the foot and ankle while weight-bearing and lifts the toes while stepping. Their use is, however, controversial. Many health care professionals traditionally discourage the use of orthoses, believing that they prevent or delay the recovery of normative movement.[3-7] Although the use of orthoses and other assistive devices, such as walking aids, is perceived to have been embraced in recent years,[6,7] studies of actual (rather than perceived) practice indicate that they are not consistently prescribed or used.[8] We therefore wished to undertake a systematic review to enable evidence-based clinical decisions to be made. There has been only 1 previous review of the effects of lower-limb orthoses,[9] which was narrative and focused on the effects of an AFO on muscle activity in the paretic lower limb. They found that the evidence for an AFO's impact on muscle activity in the paretic leg was weak, although there may be immediate kinematic and temporal improvements. No conclusion could be drawn because of large individual differences, conflicting findings, poor quality designs, and poor generalizability of the studies. Consequently, we undertook a systematic review, which included pooled meta-analysis, contemporary literature searches, and measures of balance, walking, and mobility (the effects of an AFO on biomechanic parameters are reported separately). Specifically, we wished to assess the following questions: (1) can an AFO improve balance? (2) Can an AFO improve walking? (3) Can an AFO improve mobility?

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Methods

Search strategy to identify relevant studies

The following trials registers and databases were searched: Cochrane Stroke, Movement Disorders and Injuries Groups, MEDLINE, Embase, CINAHL, AMED, PsycINFO, and the Physiotherapy Evidence Database. All searches were completed in November 2011. To identify further published, unpublished, and ongoing trials, we searched the reference lists of the articles identified, review articles, and books, and contacted the lead authors of published studies, other researchers in field clinical and research gait laboratories, and academic departments regarding relevant unpublished data or upcoming publications on ankle foot orthoses for people with stroke. English language studies were included. Abstracts were included if there was no accompanying full article and if sufficient data could be extracted or obtained from the authors. Single case designs and non-English language publications were excluded.

Keywords related to the condition include *stroke*, *hemi**, and *cerebro-vascular*; keywords related to the intervention include: *ortho**, *splint*, *calliper*, *brace*, *foot drop*, *foot*, and *ankle*.

Types of trials

The following types of trial were included: (1) randomized controlled trials that compared an AFO with no treatment, normal care, or that compared an AFO plus normal management versus normal management alone; (2) trials including adults with stroke: trials that measured lower-limb impairments, activity limitation, or the incidence of adverse events, such as pain or pressure ulcers; and (3) trials of an AFO (excluding orthotic devices that were part of a device to deliver functional electric stimulation). Interventions that were not specifically AFOs, such as taping, strapping, air-pressure splints (eg, used for positioning a limb), serial casting, a toe spreader, or shoe raises/wedges, were excluded.

Identification of relevant articles

We independently considered all titles and then the abstracts against the inclusion criteria. Then the full text of articles identified from the abstract screening was assessed. For those that met the criteria, we assessed the methodologic quality before a final decision about whether to include the article was made. Disagreements were resolved by discussion and mediation with a third person.

Data extraction

Details of the method/design, participants, orthosis used, manner of application, and outcome measures were extracted (table 1), along with the number of participants and the mean ± SD of the outcome measures for analysis. If necessary, we contacted the trialists for clarification, missing data, or both.

List of abbreviations:

AFO ankle-foot orthosis
CI confidence interval
SMD standardized mean difference

Assessment of methodologic quality

The methodologic quality of the selected trials was assessed using criteria described in the Cochrane Handbook for Systematic Reviews of Interventions[10] to assess potential sources of bias. The sources of bias recommended are: selection bias (concealment of allocation), performance bias (randomization), attrition bias (dropout rates), and detection bias (blinding of assessors). However, it is not possible to mask whether someone is wearing an AFO, and therefore this criterion was removed. Studies rated as having a low risk of bias (all criteria met) were selected for the analysis.

Analysis

Review Manager software (RevMan 5)[a] was used for the analysis. Where possible, results were combined for continuous outcomes using mean difference and 95% confidence intervals (CIs) by a fixed-effect model. Where this was not possible, studies that used different tools to measure the same underlying construct were combined using a standardized mean difference (SMD) and 95% CIs with a fixed-effect model. We attempted to use general inverse variance to analyze crossover studies, but insufficient studies reported their data in a format that could be used for this analysis. Consequently, crossover studies were analyzed as if they had used a parallel group design using the mean difference or SMD, as appropriate, although we recognized that this was likely to give a conservative estimate of the effect.[11] Comparisons that involved only 1 study were not included in the meta-analysis; these were reported qualitatively. Statistical heterogeneity was investigated using the I^2. If studies reported the effects of 2 different designs of orthosis or 2 separate groups of participants, the data from both groups were included in the analysis.

Results

Description of studies

We screened 120 abstracts and the full texts of 43 articles and identified 13 trials involving 334 patients that met the inclusion criteria and were included in the analysis (see table 1). The aim of the selected trials was to assess the immediate or short-term effect of the AFOs, and testing was completed in a single testing session, thereby avoiding the contaminating effect from rehabilitation or spontaneous recovery and minimizing the random error caused by testing over a prolonged period. No studies examined the long-term effects of wearing an orthosis. All trials used a randomized crossover design in which an AFO was compared with no AFO; the participants acted as their own controls (when walking without the orthosis), and the randomization came from the order of testing (with or without the orthosis). Because each participant received both the control and the treatment, concealment of allocation was not an issue (in that it could not be concealed; everybody received both), and this criterion was scored positively. In all the selected trials, all testing was completed in 1 day, which contributed to the zero dropout rate (in all cases). Whether analysis was undertaken on an intention-to-treat basis was therefore not an issue, and this criterion was scored positively. Sample sizes were generally small (range, 8–61 participants), and power calculations were rarely used.

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