



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tracking of the selected articles were screened, and the authors of selected trials were contacted for any further unpublished data.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 \pm 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 \pm 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 Interventions¹⁰ 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.

Table 1 Characteristics of selected studies

Study	Participants	Interventions	Outcomes and Measurement Methods
Alvin et al ¹²	8 subacute/chronic strokes, able to stand and walk alone Mean time since stroke: 21wk (range, 7–32wk) Age: 46–66y	Plastic AFO from below the fibular heads to the tips of the toes Habituation: all used an AFO in everyday life (mean, 8wk; range, 2–126d)	Balance (body sway, movements of the center of pressure measured with Kistler forceplates) Walking speed (ten-meter walk test)
Burdett et al ²²	19 chronic strokes, able to walk alone with or without a walking aid. 11 wore an AFO in everyday life 19 were tested wearing an Air-Stirrup brace; mean time since stroke \pm SD, 114 \pm 109d; mean age, 62y 11 were tested wearing their own AFO Mean time since stroke = 133 \pm 127d; mean age \pm SD, 58 \pm 13y	Air-Stirrup ankle brace Habituation: no practice time to habituate to using the Air-Stirrup and Participants' own plastic or metal-strutted AFO, previously worn in everyday life (duration not reported)	Walking speed (timed walk test >5m), Step length (inky footprints on paper over 5-m paper walkway)
Chen et al ¹³	24 chronic strokes, able to stand without external support for 60s, 20 patients used a walking aid Mean time since stroke, 13mo (range, 3–120mo); mean age, 59y (range, 43–76y)	Anterior plastic AFO. Habituation: all existing anterior AFO users	Balance (postural sway and symmetry) using a computer dynography forceplate system
Corcoran et al ¹⁴	15 chronic strokes able to walk at least 300m (1000ft) Mean time since stroke, 40mo (range, 5–168mo); mean age, 45y (range, 11–56y)	Metal and plastic AFO Habituation: participants used each brace for at least a week before testing	Maximum and comfortable walking speeds (30-m timed walk test) Mobility (time to ascend and descend stairs)
de Wit et al ¹⁵	20 chronic stroke patients able to walk independently recruited from rehabilitation centers Mean time since stroke, 26mo (range, 8–48mo); mean age, 61y (range, 41–73y)	Participants' own plastic AFO Habituation: all wore an AFO in everyday life for at least 6mo Mean usage time, 21mo (range, 6–44mo)	Walking speed (ten-meter walk test) Mobility (Timed Up & Go test)
Gök et al ²¹	12 subacute/chronic strokes, able to walk independently using a walking aid Mean time since stroke, 67d (range, 30–270d); mean age, 54y (range, 39–65y)	Plastic and metal AFO Habituation: participants given opportunity to practice but not reported how long	Walking speed, step length (using Vicon motion analysis system)
Hesse et al ²³	19 subacute/chronic strokes undergoing rehabilitation, able to walk at least 20m alone and with marked plantar flexor spasticity Mean time since stroke, 5mo (range, 1.5–16mo); mean age, 55y (range, 30–79y)	Valens (single strut metal AFO attached to heel of shoe) Habituation: newly fitted AFO (<1wk to practice using it)	Walking speed (ten-meter walk test) Stride length (calculated from the number of steps taken to complete the ten-meter walk test)
Hesse et al ²⁴	21 subacute/chronic strokes undergoing rehabilitation, able to walk at least 20m alone and with marked plantar flexor spasticity Mean time since stroke, 5mo (range, 1.5–16mo); mean age, 58y (range, 30–79y)	Valens (single strut metal AFO attached to heel of shoe) Habituation: newly fitted AFO (<1wk to practice using it)	Walking speed (ten-meter walk test) Stride length (calculated from the number of steps taken to complete the ten-meter walk test)
Pohl and Mehrholz ¹⁶	28 (20 subacute/chronic strokes, 8 head injuries) undergoing rehabilitation and able to walk 15m alone Mean time since stroke, 2.6mo (range, 1–6mo); mean age, 52y (range, 23–77y)	Short plastic AFO Habituation: worn AFO in everyday life for <1wk	Balance (postural sway and weight distribution) using ADDON forceplate system

(continued on next page)

Table 1 (continued)

Study	Participants	Interventions	Outcomes and Measurement Methods
Simons et al ²⁰	20 subacute/chronic strokes Able to walk at least 10m and stand unaided for 90s; Mean time since stroke, 39mo (range, 5–127); mean age, 57y (range, 36–78y)	Habituation; worn AFO in everyday life for at least 2mo (mean, 35mo; range, 12–123mo) Used a range of plastic or metal rigid or hinged AFOs	Mobility (Timed Up & Go test, Functional Ambulation Categories) Walking speed (ten-meter walk test) Balance (Berg Balance Scale and weight distribution measured using force plates)
Tyson and Thornton ¹⁷	25 subacute/chronic strokes undergoing rehabilitation, able to weight bear and step with weak leg (but may be unable to walk functionally in everyday life) Mean time since stroke \pm SD, 8 \pm 6mo; mean age, 50 \pm 1y	Hinged custom-made AFO Habituation: participants wore the AFO in everyday life for at least 1wk before testing	Mobility (Functional Ambulation Categories), Walking speed (five-meter walk test) Step length (inky footprints on paper over 7-m paper walkway)
Tyson and Rogerson ¹⁹	20 subacute strokes undergoing rehabilitation, able to weight bear and step with weak leg (but unable to walk functionally in everyday life) Mean time since stroke, 6.5wk; mean age \pm SD, 66 \pm 10y	Off the shelf plastic AFO Habituation: the morning before testing	Mobility (Functional Ambulation Categories) Walking speed (five-meter walk test) Step length (calculated from the number of steps taken to complete the five-meter walk test)
Wang et al ¹⁸	61 chronic strokes, able to stand without support for 1min and walk 10m with an assistive device Mean time since stroke \pm SD, 1044 \pm 1105d; mean age \pm SD, 62 \pm 12y and 42 acute/subacute strokes (<6-mo duration) recruited from same sources and inclusion criteria Not stated whether participants were receiving rehabilitation Mean time since stroke \pm SD, 101 \pm 51d; mean age, 60 \pm 13y	Plastic AFO Habituation: not reported	Balance (Berg Balance Scale) Weight distribution and postural sway measured using BalanceMaster forceplate system) Walking speed (ten-meter walk test)

All the trials compared an AFO with no AFO, but there was no consistency in the design of AFO used. Most AFOs were made of plastic,^{12–20} custom-made,^{12–14,16,17,21} rigid (ie, with the ankle joint fixed),^{12–22} and used a posterior leaf design (with the shaft of the AFO covering the calf).^{12,14–17,19,20} However, alternative types were also tested, these included off-the-shelf,^{15,18–20,22–24} anterior leaf (covering the shin),¹³ short (only extending above the malleoli),¹⁶ and hinged (at the ankle)^{17,20,23,24} designs. Metal AFOs were tested as well as those made of plastic.^{14,20–24} Most extended to the end of the toes, but designs in which the AFO was fixed into the heel of a shoe^{14,20–24} or terminated at the metatarsal heads^{13,16,20} were also used.

Three studies compared different designs of AFOs with each other as well as with no AFO^{14,21,22}; 2 studies^{14,21} compared a plastic and metal AFO, while Burdett et al²² compared the participants' usual AFO (either metal or plastic) with an Air-Stirrup ankle brace (traditionally used to treat ankle inversion injuries). This type of brace could be excluded from the trial, because strictly speaking, it is not an AFO (its aim is to limit inversion rather than plantarflexion, and it only acts over the ankle joint, rather than the ankle and intrinsic joints of the foot). However, it is included here, because it is commonly used as if it were an AFO. A comparison of different types of orthoses was not

one of the review's objectives, but the data from each AFO in comparison with no AFO was included in the analysis. One trial²⁰ recruited habitual AFO users who used a range of AFO designs (metal and plastic, articulated and nonarticulated). These data were analyzed together.

The inclusion criteria for the trials were broad; most studies merely stated that the participants needed to have had a stroke, be able to give informed consent, and fulfill minimum mobility (or balance) criteria. There were 5 exceptions^{16,17,19,23,24} that specified that participants should be free of contracture at the affected ankle. Two of these studies^{23,24} also specified that the participants should have marked spasticity at the affected ankle (grade 3 on the modified Ashworth Scale), while Gök et al²¹ specified participants needed to have no ankle control on the hemiplegic side. Few studies gave any details of how the participants were recruited, and most studies appeared to be convenience samples of past patients who were already known to the service. Most participants were in the chronic stages after stroke and no longer receiving rehabilitation,^{12–15,18,20,22} although 6 studies^{16,17,19,21,23,24} involved people in the acute or subacute stages who were undergoing rehabilitation.

Nine studies assessed the effects of the AFO on walking. In all but 2 studies, the participants were able to walk without

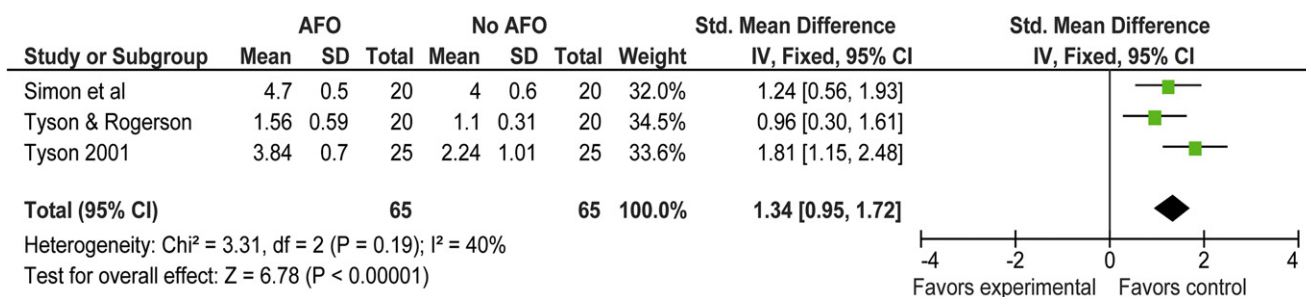


Fig 1 Forest plot of the effects of an AFO on mobility. NOTE. Because of the crossover trial design, the numbers appearing in the treatment (AFO) and control (no AFO) columns are the same participants. Abbreviations: IV, inverse variance; Std., standard.

assistance, but the minimal inclusion criteria were wide ranging, from merely walking without the assistance of a walking aid^{15,21,22} to walking at least 300m (1000ft).¹⁴ The exceptions were the trials by Tyson et al,^{17,19} which included more disabled patients who were undergoing gait rehabilitation but could not yet walk in everyday life. The wide inclusion criteria were reflected in the variability of participants' mobility levels, which ranged from .18m/s¹⁷ to .84m/s¹⁴; however, for all studies, the mean walking speed was well below that of healthy older men and women (1.18m/s and .96m/s, respectively^{25,26}). Four studies considered the effect of an AFO on balance. For these, the minimal inclusion criteria were for participants to be able to stand without external support for 20 seconds,¹⁶ 60 seconds,^{13,18} or 90 seconds²⁰ and perform weight-shift movements¹³ or withstand external perturbations.²⁰ Most studies recruited participants who already used an AFO, but in 5 studies,^{14,17,19,23,24} the AFOs had been fitted for ≤ 1 week. For 3 studies,^{15,16,21} the habituation time was unreported, and it appeared that the participants had minimal practice using the AFOs before testing.

The most frequent outcome measure was walking speed and step/stride length followed by measures of balance (postural sway, weight distribution while standing). Other measures of mobility were the ability (time taken) to get up and down stairs, the Timed Up & Go test,²⁷ and the Functional Ambulation Categories.^{17,19,20} Adverse events and other impairments, such as spasticity, have not been considered in any of the trials.

Statistical heterogeneity

The included trials showed marked homogeneity in the study design and intervention offered, although the participants' level of disability and the design of the AFO studied varied. Consequently, a fixed-effect model was used for all other comparisons. Given the

very low statistical heterogeneity, a sensitivity analysis was not necessary.

Effects on mobility

Three studies^{17,19,20} involving 65 participants reported the effects on mobility using the Functional Ambulation Categories.²⁸ Because this is an ordinal scale, an SMD was used for the analysis.¹⁰ Both trials by Tyson et al^{17,19} reported median values, but we calculated the mean \pm SD from the original data for the analysis. All studies favored the AFO, and the effect was significant (SMD, 1.34; 95% CI, .95–1.72; $P < .001$), indicating that participants walked more independently with an AFO (fig 1).

Effects on time taken to negotiate a flight of stairs (s)

Two studies^{14,15} involving 35 participants compared the time taken to negotiate a flight of stairs (s) with and without an AFO. Corcoran et al¹⁴ reported the effects of a metal and a plastic AFO, and therefore the results of both AFOs are included. Although the units of measurement were the same (s), it was not clear whether the flights of stairs used were standardized, and therefore an SMD was used. All the comparisons favored an AFO, in that participants negotiated the stairs faster when using an AFO. However, the difference failed to reach statistical significance (SMD, $-.37$ s; 95% CI, $-.77$ to $.03$; $P = .07$) (fig 2).

Effects on the Timed Up & Go test (s)

Two studies,^{15,20} involving 40 participants, reported the effect of an AFO on the Timed Up & Go test. This is a measure of mobility in which the time taken to rise from a chair, walk a short distance, turn around, return, and sit down is measured.²⁷

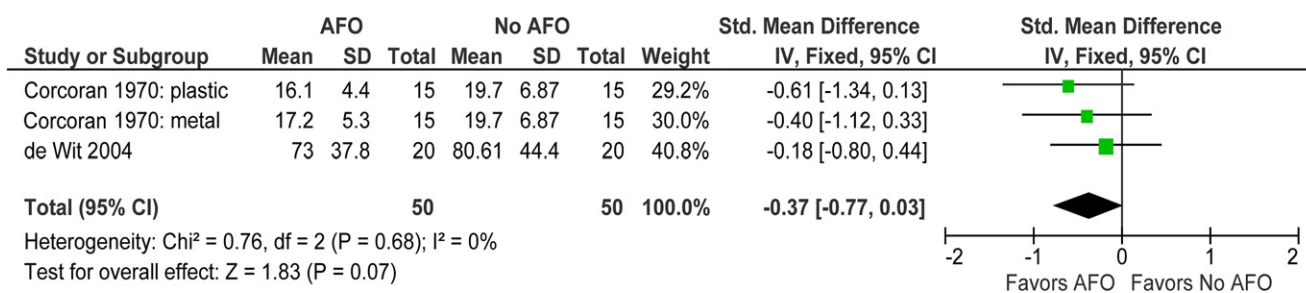


Fig 2 Forest plot of the effects of an AFO on the time taken to negotiate a flight of stairs (s). NOTE. Because of the crossover trial design, the numbers appearing in the treatment (AFO) and control (no AFO) columns are the same participants. The total number of participants differs from the text, because some participants were tested with >1 type of AFO.¹⁴ Abbreviations: IV, inverse variance; Std., standard.

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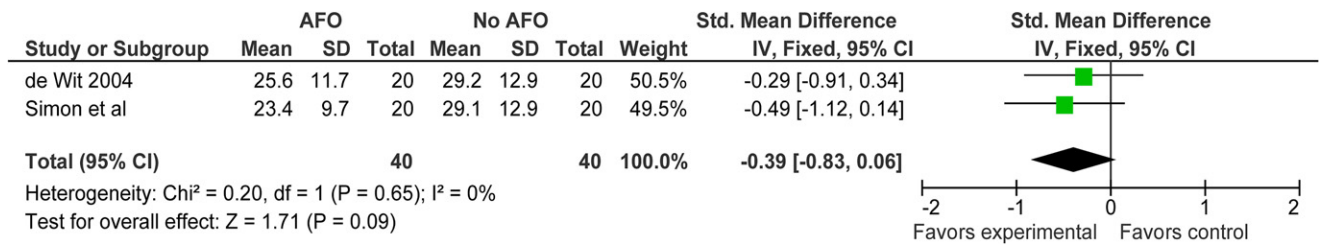


Fig 3 Forest plot of the effects of an AFO on the Timed Up & Go test (s). NOTE. Because of the crossover trial design, the numbers appearing in the treatment (AFO) and control (no AFO) columns are the same participants. Abbreviations: IV, inverse variance; Std., standard.

Although the same test was used in both trials, the way in which it was operationalized may have differed (eg, with a different chair); therefore, SMDs were calculated. Both comparisons favored an AFO, in that participants performed the test faster when using an AFO. However, the difference failed to reach statistical significance (SMD, $-.39$ s; 95% CI, $-.83$ to $.06$ s; $P = .09$) (fig 3).

Effects on walking speed (m/s)

Eleven studies reported the effects on walking speed (m/s) involving 282 participants,^{12,14,15,17-24} including 3 in which >1 type of AFO was assessed. Burdett et al²² compared both an Air-Stirrup ankle brace and the participants' own AFO with no AFO; Corcoran,¹⁴ Gök,²¹ and colleagues reported the effects of a plastic and metal AFO. Wang et al¹⁸ involved 2 separate groups of participants: 1 group with a stroke of short duration and the other with a stroke of a longer duration. All data were included, which involved 50 participants who were tested using >1 orthotics; hence the discrepancy between the number of participants ($n=250$) and the total participants shown in figure 2. There was a significant beneficial effect (mean difference, $.06$; 95% CI, $.03-.08$; $P < .0001$), indicating that participants walked faster when using an AFO than without (fig 4).

Effects on step or stride length (m)

Seven studies, involving 144 participants, reported the effects of an AFO on step or stride length.^{12,17,19,21-24} Data from the affected leg were extracted. Where both step and stride length were reported, only the data for step length were extracted (as stride length is a function of step length). Gök et al²¹ reported the effects of a metal and plastic AFO, while Burdett et al²² reported the effects of the participants' normal AFO (plastic or metal) and an Air-Stirrup ankle brace. Data from all the different designs were included. Because 2 different parameters (step or stride length) using the same unit of measurement (m) were extracted, an SMD was used. All studies favored the AFO, and the effect was significant (SMD, $.28$ m; 95% CI, $.05-.51$; $P = .02$), indicating that participants had a longer step and stride length when using an AFO compared with no AFO (fig 5).

Effects on balance

Two studies involving 122 participants reported the effects of an AFO on balance^{18,20} using the Berg Balance Scale.²⁹ However, Wang et al¹⁸ did not report any SD data, and therefore it could not be entered in to the meta-analysis. Wang reported that the AFO had no significant effect on balance in either the group of participants with a short duration of stroke (<6 mo, $P = .862$) or

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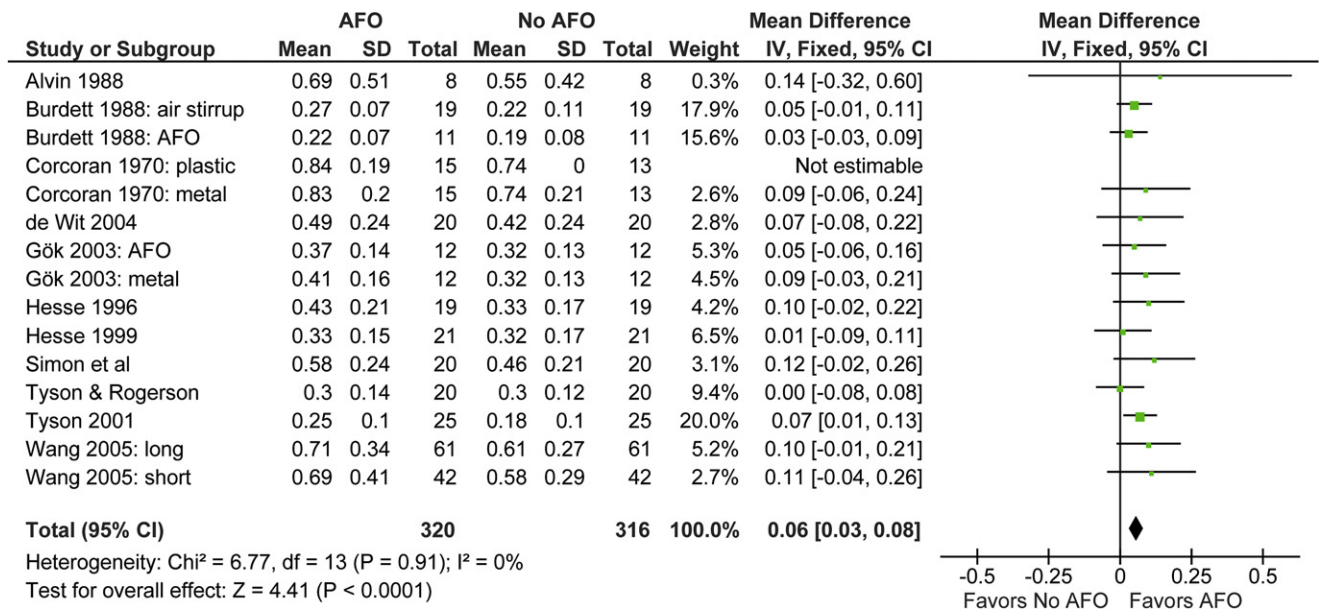
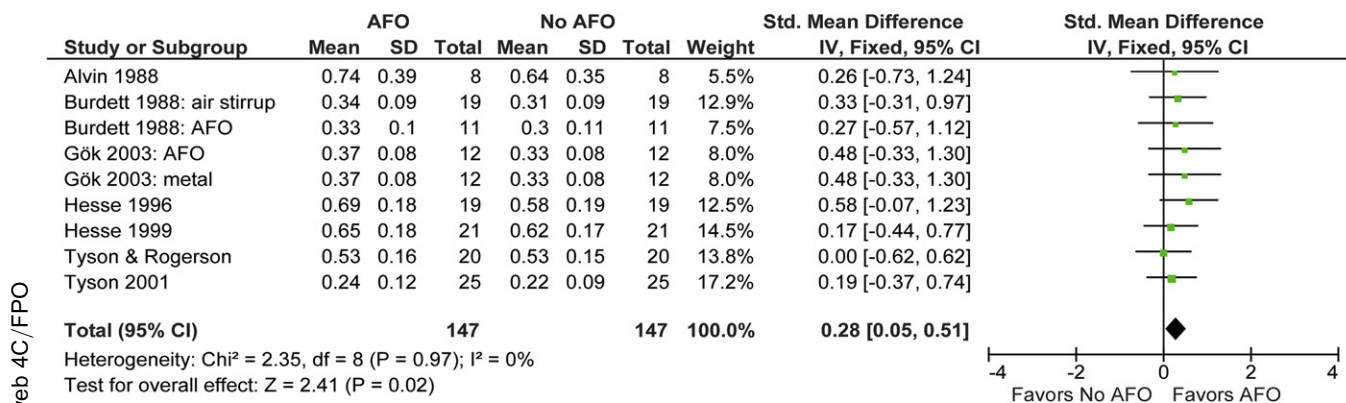


Fig 4 Forest plot of the effect of an AFO on walking speed (m/s). NOTE. Because of the crossover trial design, the numbers appearing in the treatment (AFO) and control (no AFO) columns are the same participants. The total number of participants differs from the text, because some participants were tested with >1 type of AFO.^{14,21,22} Abbreviation: IV, inverse variance.



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Fig 5 Forest plot of the effects of an AFO on weak step or stride length (m). NOTE. Because of the crossover trial design, the numbers appearing in the treatment (AFO) and control (no AFO) columns are the same participants. The total number of participants differs from the text, because some participants were tested with >1 type of AFO.^{21,22} Abbreviations: IV, inverse variance; Std., standard.

a longer duration (>12mo, $P = .553$). However, both groups had a mean score of 51 (out of 56). Ceiling effects have been reported for the Berg Balance Scale,²⁹ and this may be a factor for these more able groups. Simons et al²⁰ reported that an AFO had a significant effect in that participants had better balance when wearing the AFO (mean \pm SD, 48.09 ± 4.8 with an AFO vs 46.2 ± 5.5 without an AFO; $P = .001$).

Effects on weight distribution while standing

Five studies involving 183 participants reported the effects of an AFO on measures of the symmetry of weight distribution.^{12,13,16,18,20} Data from Wang et al¹⁸ included a group of participants with a short duration since stroke and a separate group who had a longer duration (>6mo). Data from the 2 groups were presented separately. There was significant improvement in the symmetry of weight distribution with an AFO (SMD, $-.32$; 95% CI, $-.52$ to $-.11$; $P = .003$), indicating that patients bore more weight through their weak leg (fig 6).

Effects on postural sway

Four studies involving 163 participants assessed the effect of an AFO on balance impairments using measures of postural sway.^{12,13,16,18} Data from Wang et al¹⁸ included a group of participants with a short duration since stroke and a separate group who had a longer duration (>6mo). Although all the studies favored the AFO (indicating that participants had less postural

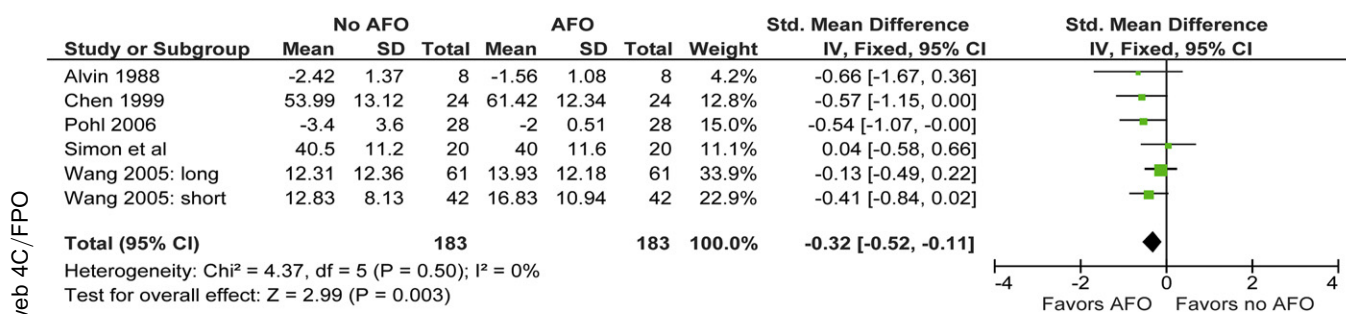
sway when using the AFO), the comparison failed to reach statistical significance (SMD, $-.18$; 95% CI, $-.40$ to $.04$; $P = .10$) (fig 7).

Discussion

This systematic review assessed the effects of an AFO on balance, walking, and mobility for people with stroke. The available evidence suggests that an AFO can improve these factors, but only the immediate, short-term effects have been assessed. The effects on other aspects of mobility and balance (postural sway and timed mobility tests) showed a positive trend favoring an AFO but failed to reach statistical significance, while the effects on functional balance were mixed. The small numbers of included participants and the closeness of the CIs to zero suggest these comparisons may be underpowered; further trials to generate a larger dataset are needed.

We are satisfied that the risk of publication bias is low. Our literature search was comprehensive and extensive, and we contacted original trialists and other researchers working in the field of stroke rehabilitation, orthotics, and gait analysis research. However, we only included studies published in English, and therefore some trials in other languages may have been missed.

The selected studies all used a crossover design to assess the immediate effects of an AFO compared with no AFO. This was an optimal design to address the objective of the studies. A crossover design was appropriate, because it can reasonably be expected that an AFO (or no AFO) would not have a carryover



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Fig 6 Forest plot of the effects of an AFO on weight distribution. NOTE. Because of the crossover trial design, the numbers appearing in the treatment (AFO) and control (no AFO) columns are the same participants. Abbreviations: IV, inverse variance; Std., standard.

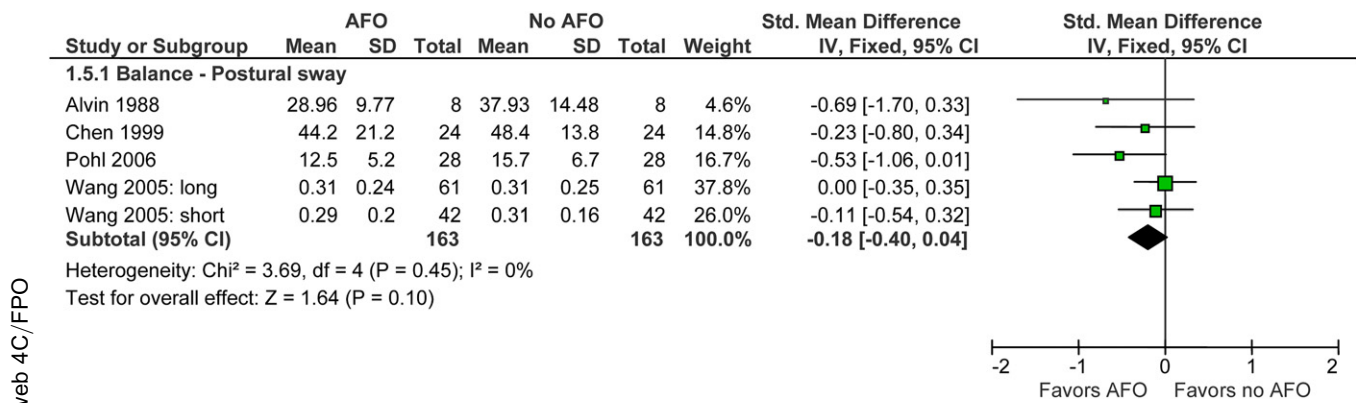


Fig 7 Forest plot of the effects of an AFO on postural sway. NOTE. Because of the crossover trial design, the numbers appearing in the treatment (AFO) and control (no AFO) columns are the same participants. Abbreviations: IV, inverse variance; Std., standard.

effect between testing sessions, and it has the advantage of reducing the effect of heterogeneity between participants, thereby minimizing the required sample size. All the testing was completed in 1 day, and dropout rates were zero, and because all of the participants received both treatments (AFO or no AFO) concealment of allocation was not an issue. The studies were randomized in that the order of testing was randomized, although there were rarely details of the method of randomization. None of the studies were blinded for either participants or assessors. This is reasonable, because it is not possible to mask whether someone is wearing an AFO; however, it is a possible source of bias. One way of overcoming this is to use automated measurement tools, but these were used inconsistently in the selected studies.

The finding that an AFO is beneficial, at least in the short-term, is important: it shows that an AFO works. However, although clinically relevant, it is at an insufficient level to fully inform clinical practice, and many crucial questions remain unanswered. Clinicians need to know the best type of AFO to prescribe, for whom they should be prescribed, the optimal time to prescribe one, how long they should be used, the adverse effects, and the factors influencing acceptability and adherence to their use. It is particularly important that these factors are investigated in the long-term, because most patients are prescribed an AFO for long-term use. These are complex questions, the answers to which probably differ according to the patients' level of, and combination of, impairments. Further phase II exploratory/intervention modeling studies are needed to truly understand the optimal way in which an AFO should be prescribed and used, both during rehabilitation, as an adjunct to other rehabilitation interventions (which may allow earlier and more active mobilization), and in the long-term. This information can then be used to inform phase III definitive, pragmatic trials to fully consider clinical and cost effectiveness.

Participants were generally a convenience sample of past patients or patients known to a rehabilitation or orthotics service, which could constitute a biased sample of patients who were satisfied with the AFO and found it beneficial. Despite the convenience sampling methods, the participant descriptions (summarized in table 1) suggest that the recruited samples were reasonably representative and the results generalizable, although further pragmatic studies would be needed to confirm this. Few reported any sample size calculations and, although the significant results indicate that statistical power was reached, none were powered to assess the clinical significance. There are no

generally accepted measures of clinical significance in this field; only 1 study¹⁵ attempted to define and assess the clinical significance of changes when using an AFO. They used the Walking Handicap Scale to define a clinically significant change in walking speed as 0.2m/s (based on the change needed to move from 1 category of the Walking Handicap Scale to another). This represents an increase of 20% of normative walking speed (generally considered around 1m/s²⁵) or 27% of the mean walking speed for the most able participants in this review (.84m/s¹⁴) and 111% of the least able (.18m/s¹⁷). Although an improvement of around 30% might be considered a reasonable treatment effect, over 100% is ambitious, and this may explain why the reported changes failed to reach these predefined levels of significance.

Given the variability in the walking speed of people with stroke, it is unlikely that a single value will be relevant to all patients. A more appropriate method may be to calculate an individual's percentage improvement, which has the advantage of universality, thereby enabling heterogeneous groups to be compared. However, there is no generally accepted definition of the percentage improvement needed to represent a clinically relevant change; values ranging from 10% to 50% are widely used in the literature, usually with no justification for their choice. If values of 10% to 20% were chosen, the results of this review would suggest that an AFO produced a clinically relevant improvement. If a value of 50% was chosen, then the results would suggest that an AFO produced a clinically relevant improvement for the most impaired patients but not the more able. An alternative approach may be to investigate the functional changes individual patients find relevant and satisfactory. A small change in walking speed may be of great importance to a patient if it enables them to get to the toilet effectively, for example, but it may be of little importance to a more able patient, who may wish to be able to walk longer distances outside.

Study limitations

As previously discussed, the main limitations of the generalizability of this review lies in the nature of the data selected. The trials all assessed the immediate effects of AFOs in a convenience sample in terms of the participants' characteristics and the sample size. Powered sample size calculations were lacking and clinical, rather than statistical, significance was generally

unconsidered. Several of the comparisons made were probably underpowered. To progress the evidence base regarding orthotics for people with stroke, researchers in the field need to address these methodologic limitations and move on from the relatively convenient and simple exploratory phase II trials of immediate effect to pragmatic parallel group trials of clinical and cost effectiveness, which have the potential to impact on clinical practice and patient outcomes.

Conclusions

Using an AFO can make an immediate improvement in mobility (functional ambulation categories), walking (speed and step/stride length), and some aspects of balance (weight distribution in standing) while the AFO is worn. The AFO did not affect other aspects of mobility (timed stair climb and Timed Up & Go test) and balance (postural sway). The results support the use of an AFO to improve walking and some aspects of balance; however, the long-term effect of AFO usage has not been investigated, and should be a priority.

Supplier

a. Cochrane IMS. Available at: <http://ims.cochrane.org/>.

Keywords

Orthotic devices; Rehabilitation; Stroke; Walking

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