AAOP State-of-the-Science Evidence Report: The Effect of Ankle-Foot Orthoses on Balance-A Systematic Review

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ABSTRACT

Ankle-foot orthoses (AFOs) are typically designed to limit the motion of the ankle joint in one or more planes. Given that balance may be compromised when joint range of motion is restricted, an understanding of the relative effects of AFOs on balance performance is clinically relevant. The aim of this systematic review was to evaluate existing evidence related to the effects of AFOs on static and dynamic balance. A search of appropriate medical databases was conducted, and 37 articles were found to satisfy predetermined inclusion criteria. Articles were categorized under two main areas: those investigating the use of AFOs designed for sporting applications (sports orthoses, 18 studies) and those investigating orthoses that are intended to facilitate ambulation in subjects with locomotor disorders (ambulatory orthoses, 19 studies). Combined results suggest that sports orthoses may facilitate certain aspects of balance in subjects with ankle instability and that balance is unlikely to be compromised when able-bodied subjects wear AFOs as a prophylactic measure. No evidence exists to suggest that any one design of sports orthosis is superior to another in terms of performance on balance measures. Results of studies involving ambulatory orthoses indicated that their effects on balance were largely dependent on the design characteristics of the orthosis used. Rigid AFOs seemed to facilitate static balance tasks, although the level of confidence in this outcome was relatively low. Under dynamic conditions, rigid AFOs seemed to compromise balance for the tested populations; confidence in this outcome was rated as moderate. A high level of confidence was ascribed to the statement that leaf spring AFOs, which allow controlled motion in the sagittal plane, seemed to facilitate both static and dynamic balance in the studied cohorts. (J Prosthet Orthot. *2010;22:P4–P23.)*

Ankle-foot orthoses (AFOs) are commonly prescribed for pathological conditions affecting joint stability, positioning, pressure distribution, and neuromuscular insufficiencies. They have been demonstrated to affect numerous gait parameters including temporospatial variables,[1,2] joint kinematics and kinetics,[3,4] and energetics.[5–7] Given that AFOs, by design, limit the motion of the ankle joint in one or more planes of motion, an understanding of the relative effects that they may have on balance is of clinical importance. The aim of this article is to systematically review literature related to AFOs and the relative effects they may have on static and dynamic balance.

BACKGROUND

For the purposes of this review, an AFO is defined as "an orthosis which encompasses the ankle joint and the whole or part of the foot" (ISO 8549-3:1989). Based on this definition, the term AFO encompasses a wide range of devices of varying construction and design. These range from flexible elastic supports to rigid plastic or carbon fiber designs.

AFOs are often used in the management of various pathological conditions that affect normal functioning of the ankle joint complex. Such conditions include stroke, cerebral palsy, multiple sclerosis, rheumatoid arthritis, and both functional and mechanical ankle instabilities. They are also widely used by athletes as a prophylactic measure to avoid ankle injuries or to stabilize the ankle joint after an isolated injury. In this review, the authors make the distinction between articles investigating sports orthoses and those investigating orthoses that are required to facilitate ambulation because of an underlying pathological condition (ambulatory orthoses).

For the purposes of this review, sports orthoses are classified as any device that provides external support to the ankle with the aim of stabilizing the joint after an isolated injury or with the aim of preventing injury. The mechanism by which this is achieved can be mechanical (i.e., the orthosis is designed to enhance stability) and/or neurophysiological (i.e., the orthosis is designed to enhance proprioceptive feedback). AFOs for sporting applications are typically designed as variations of three general constructions with increasing stiffness; elastic supports, lace-up canvas orthoses, or semi rigid orthoses.

When patients have a pathological condition and the major function of the AFO is to influence joint alignments, improve posture, or compensate for neurological deficiencies, the authors choose to group the orthoses under the term ambulatory orthoses. Numerous orthotic designs can be categorized under this heading. Designs most commonly described in literature are presented below:

- Floor reaction orthosis (also known as ground reaction AFOs): this design prevents dorsiflexion beyond a set limit and in doing so generates an external extension moment at the knee.
- Rigid AFO: a construction aiming to restrict range of motion in all planes.
- Nonrigid AFO: allows range of motion in one or more planes. This category can include articulated AFOs and those orthoses in which flexibility is achieved through the choice of material and design characteristics of the device.
- Leaf spring AFO: a specific version of a nonrigid AFO that is designed to assist dorsiflexion of the foot but permits stance phase plantarflexion.
- Supramalleolar orthosis (SMO; also known as a dynamic AFO DAFO): this design uses a nonarticulated flexible shell encompassing the foot to maintain or improve the coronal alignment of the subtalar joint but does not affect sagittal ankle kinematics.

Given that this review focuses on the influence of different AFOs on balance, a basic understanding of balance theory is considered necessary. Balance is a complex skill necessary to maintain the body's centre of gravity within the base of support while stationary (static balance) and to control the centre of mass in dynamic situations such as walking or when subject to a destabilizing event (dynamic balance). There is a great deal of available literature detailing the physiological mechanisms that contribute to the maintenance of balance. Most recent theories suggest a multisystem approach involving cognitive, motor, cerebellar, vestibular, and proprioceptive systems[8–10] (Figure 1). The relative contribution of each of these systems in maintaining balance is context dependent and also influenced by age and pathology.[10] One of the most important biomechanical constraints on balance is a patient's ability to maintain their centre of mass within their base of support or within their "limits of stability."[9] Limitations to joint range of motion, muscle strength, and sensory input can all significantly affect these stability limits.

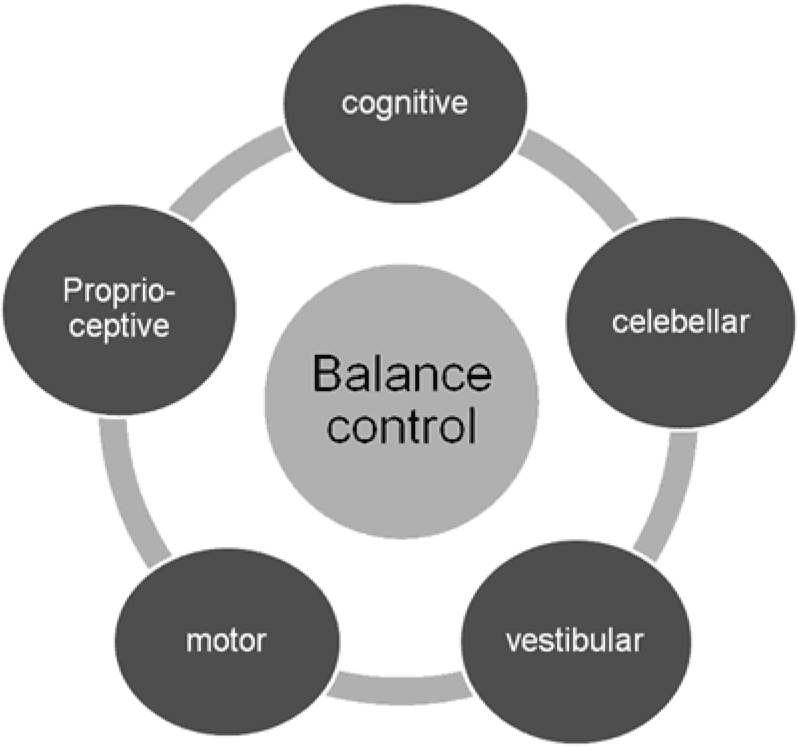

Figure 1. Mechanisms that contribute to the maintenance of balance.

The motor control component of balance can be influenced by the inherent mechanical stability offered by many AFO designs. AFOs are typically constructed to restrict rotational and translational motion.[11] When muscle strength and joint integrity are compromised, the restriction in range of motion offered by an AFO may facilitate balance by controlling or preventing inappropriate motion. In certain situations, however, it is possible that the restriction in ankle range of motion imposed by an AFO may compromise the subjects' stability limits and negatively affect balance. It is important that clinicians involved in the prescription of AFOs are able to determine when an AFO is likely to compromise balance and to weigh the risks associated with this against other benefits the patient will experience when fitted with the device.

Proprioception can be defined as the ability to detect input from mechanoreceptors, nociceptors, and muscle afferents. It is of particular importance for position sense, feedback for motor control, and dynamic joint stability.[12] Numerous pathological conditions have been demonstrated to compromise joint proprioception including arthritis,[13] peripheral nervous system disorders,[14] ligamentous injury,[15] stroke,[16] and cerebral palsy.[17] There has been some suggestion that pressure applied by orthoses facilitates joint proprioception by increasing afferent input to the central nervous system, primarily by cutaneous mechanoreceptors.[12,18,19] As the proprioceptive system is linked to balance ability, an understanding of the relative effects of AFOs on joint proprioception is of particular interest.

The cognitive component of balance may be influenced by AFOs by improving patients' confidence in their standing and walking abilities. Given that the use of AFOs has been demonstrated previously to improve stroke patients' confidence in performing functional tests,[20] the influence of AFOs on the cognitive component of balance is also of interest.

METHODS

Studies were considered for this review if they investigated subjects fitted with an AFO. The specific design of AFO and the underlying pathology of subjects did not affect the inclusion of articles but was noted by the authors. Studies were only included if they used a measure of static and dynamic balance as a dependent variable and were available in the English language. Articles were excluded if they were available only in an abstract form or did not present results of original research.

A search was performed in August 2009 of current contents in the MEDLINE, CINAHL, Cochrane, and RECAL databases. The search used free text words and, when appropriate, MeSH terms related to the following: "balance," "postural control," "stability," "ankle brace," and "orthoses." Figure 2 presents the results of the literature search. In total, 3235 articles were identified in the initial search. Three thousand one hundred thirty-one of these were removed after reading of the title and abstract by the first author. Forty-five articles were identified as duplicates, which were listed in multiple databases, and were also removed. The remaining 59 articles were read independently, in their entirety, by both authors. Twenty-eight of these were subsequently removed as they did not fulfill the inclusion criteria. Reference lists of all remaining articles were searched to identify articles that may have been overlooked in the initial search. Six additional articles were identified leaving a total of 37 articles in the final review (Figure 2).

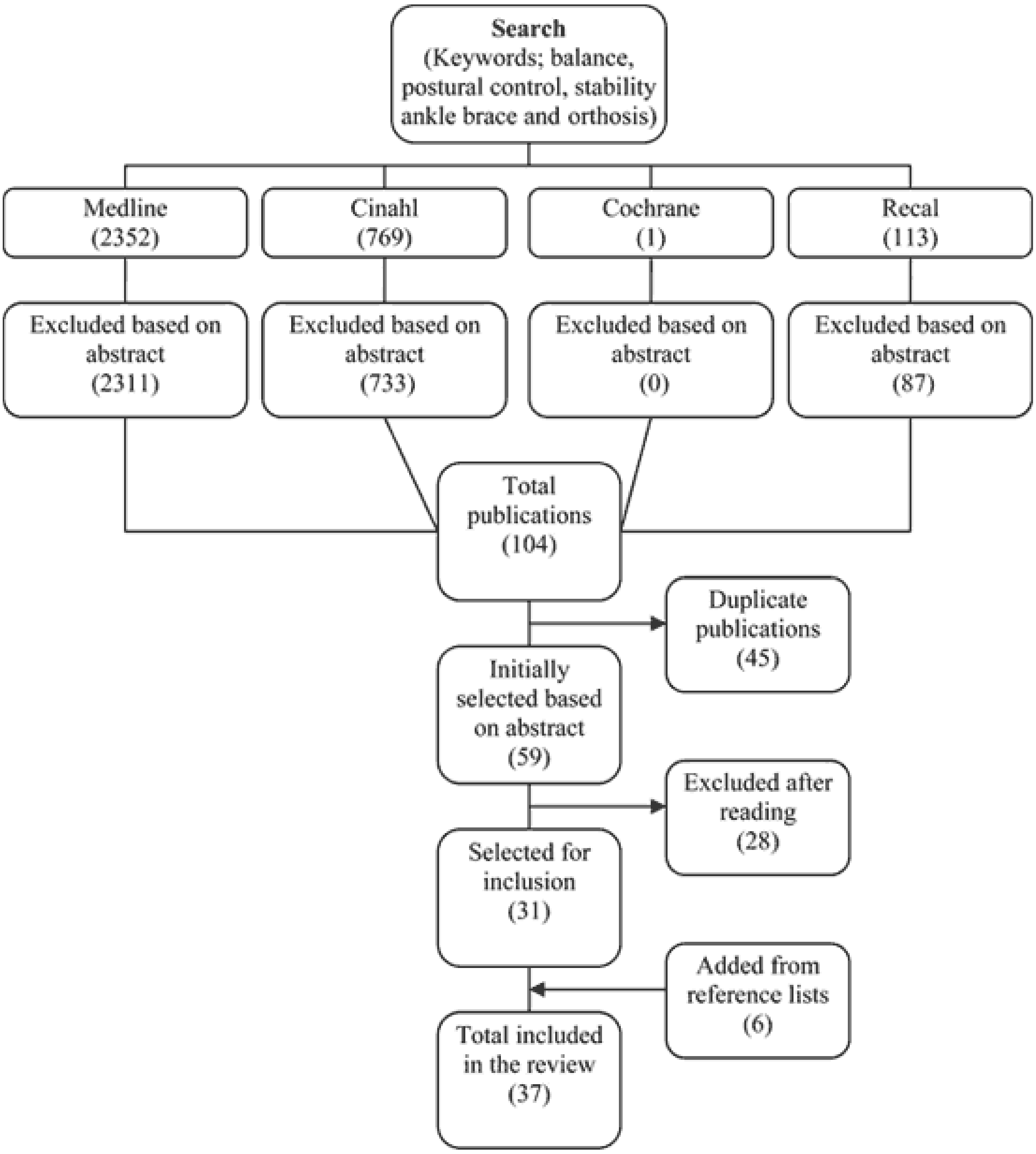

Figure 2. Results of literature search.

Methodological quality of all articles in the review was assessed independently by both authors using a modified version of the State-of-the-Science Conference (SSC) quality assessment form (Appendix A). In addition, each article was classified according to the American Academy of Orthotists and Prosthetists Study Design Classification Scale (Table 1).[21] When reviewers disagreed on points in the quality assessment form or the design classification, conflicting views were discussed until a consensus was reached.

Criterion	Yes	No	N/A	Comments
Literature review appropriate				
Inclusion or exclusion criteria appropriate				
Sample size appropriate				
Sample size justified				
Drop outs reported (number)				
Sample characteristics well described				
Control group appropriate				
Randomization (groups)				
Randomization (order of invention)				
Accommodation period				
Fatigue and learning addressed				
Groups equal at baseline				
Ethics approval reported				
Outcome measures reliable				
Outcome measures valid				
Intervention described in detail				
Intervention blinded				
Significance reported				
Statistics appropriate				
Clinical relevance reported				
Conclusions appropriate				
Free from conflicts of interest				
Overall assessment of article	High	Moderate	Low	

APPENDIX A

Table A1. Quality assessment form

Category	Rating	Type of study
Structured review	S_1	Meta-analysis
	S_2	Systematic review
(Quasi) Experimental trial	E_1	Randomized controlled trial
	E_2	Controlled trial
	E_3	Interrupted time series trial
	E_4	Single subject experimental trial
	E_5	Before-and-after trial
Observational study	O_1	Cohort study
	O_2	Case-control study
	O_3	Cross-sectional study
	O_4	Qualitative study
	O_5	Case series
	O_6	Case study
Expert opinion	X_1	Group consensus
	X_2	Individual opinion

Table 1. AAOP Study Design Classification Scale [21]

RESULTS

GENERAL OVERVIEW

A total of 37 articles were reviewed by the authors. The majority of articles had been published in the last 10 years (Figure 3) with 18 articles published since 2005. A summary of all articles included in the review are presented as Appendix B and Appendix C- *viewable as a PDFs*). The 37 articles represented publications from 25 different journals. These journals typically targeted audiences with an interest in sports science, rehabilitation, or physical therapy. All articles were experimental trials, and the large majority were classified as before and after trials (E5) (n = 25) (Figure 4).

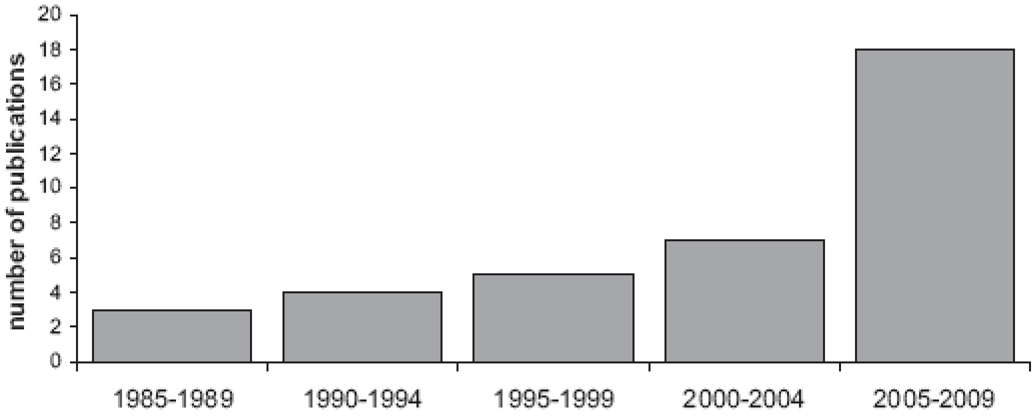

Figure 3. Number of publications by year.

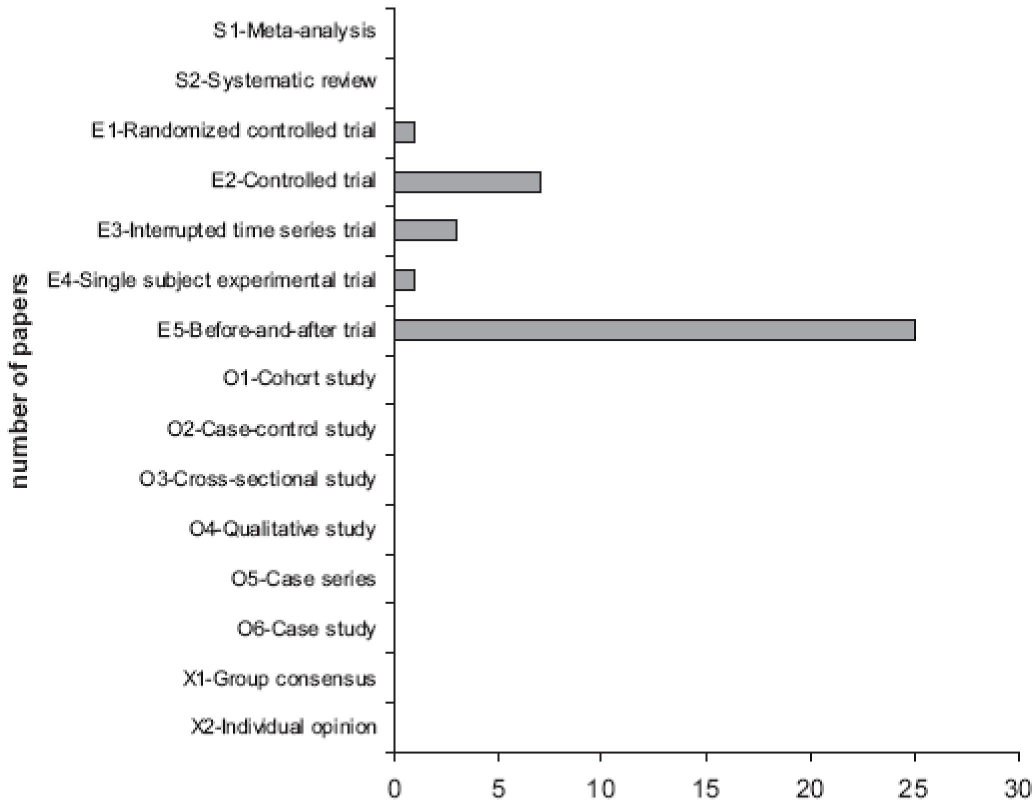

Figure 4. Type of study represented by the articles included in the review.

Eighteen articles were identified as studying orthosis for sporting applications, and nineteen were related to the use of ambulatory orthoses. In sports-related studies, the most commonly investigated orthotic designs were lace-up orthoses (11 articles) and semirigid orthoses (11 articles) with several articles investigating multiple orthotic designs. In studies targeting ambulatory orthoses, the specific designs were more varied and included rigid AFOs (7 articles), nonrigid AFOs (13 articles, including 8 articles related to leaf spring orthoses), SMOs (4 articles), and floor reaction AFOs (1 article). Numerous articles investigated more than one design of orthoses. Both custom-made and prefabricated orthoses were represented in the reviewed articles with the majority investigating prefabricated designs. Figure 5 presents an overview of the pathological conditions of subjects represented. Normal subjects used as control groups are not presented in this figure. In those studies addressing orthoses for sporting applications, the majority evaluated normal subjects (n = 13). Stroke patients and subjects with cerebral palsy were the most frequently investigated populations in the articles involving ambulatory orthoses (10 and 5 articles, respectively).

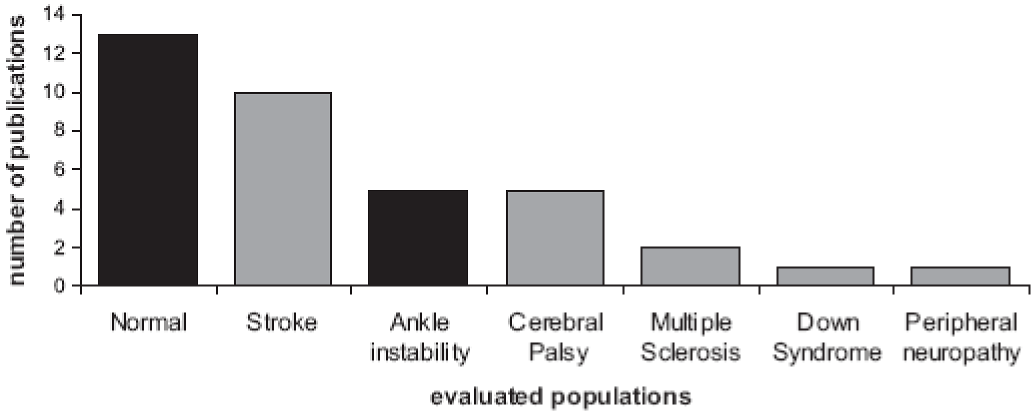

Figure 5. Number of publications by pathology. Black bars represent articles investigating sports orthoses, whereas grey bars represent articles investigating ambulatory orthoses. Normal subjects used as a control group are not represented in this figure.

BALANCE MEASURES

A wide range of balance-related outcome measures were used in the reviewed articles. These ranged from relative simple clinical tests, such as the Berg Balance Scale,[22,23] the Balance Error Scoring System (BESS),[24] the Timed Up and Go Test,[20,25–27] and the Pediatric Balance Scale,[28] to sophisticated laboratory tests performed with specifically designed balance testing equipment, including a moveable force plate and visual surround (Table 2).[29,30]

	Outcome measure	Validity established	Reliability established	Reference(s)
Clinical tests	Berg Balance Scale	Satisfactory	Satisfactory	[34,35]
	Timed Up and Go Test	Satisfactory	Satisfactory	[36,37]
	Equiscale Test	Satisfactory	Satisfactory	[31]
	Standardized walking obstacle course	Satisfactory	Satisfactory	[38,39]
	Bruininks-Oseretsky Test of Motor Performance	Satisfactory	Satisfactory	[40]
	Balance error scoring system	Satisfactory	Satisfactory	[41]
	Timed single-limb balance (eyes open)	Varied results	Satisfactory	[32,33,42,43]
	Pediatric Balance Scale	Not found	Satisfactory	[44]
	Timed single-limb balance (eyes closed)	Not found	Varied	[33,43]
	Star excursion balance test	Not found	Varied	[45]
	Timed standing balance (bipedal)	Not found	Not found	
	Touch with contralateral foot when in single-limb stance	Not found	Not found	
	Pedriö Test	Not found	Not found	
	Timed balance on a balance platform	Not found	Not found	
	Self-reported stability	Not found	Not found	
Laboratory-based tests	Sway of the GRF	Satisfactory	Satisfactory	[46]
	Limits of Stability Test	Satisfactory	Satisfactory	[47,48]
	Sensory Organization Test	Satisfactory	Satisfactory	[49]
	Ankle or hip balance strategy	Satisfactory for ankle strategy	Not found	[50]
	CoP displacement	Not found	Satisfactory	[51]
	CoP sway velocity	Not found	Satisfactory	[52,53]
	Latency of muscle activation after external perturbation	Not found	Satisfactory	[54]
	Gait symmetry index (stance)	Not found	Satisfactory	[55]
	Muscle sequencing	Not found	Not found	
	Craniocorpography	Not found	Not found	
	Weight distribution between left and right legs	Not found	Not found	
	Gait symmetry index (swing)	Not found	Not found	
	Time to stabilize GRF after a jump	Not found	Not found	
	CoP sway area	Not found	Poor	[51]
	CoP sway frequency	Poor	Poor	[53,56]

GRF, ground reaction force; CoP, center of pressure.

Table 2. Outcome measures used in reviewed studies and whether the authors were able to locate a reference demonstrating that the measure is reliable and/or valid

Several of the clinical measures used in the reviewed articles are correlated with other balance-related risk factors that are relevant to populations typically fitted with AFOs. For example, scores on the Berg Balance Scale have been demonstrated as predictive of an increased risk of falls in a variety of populations including the elderly,[57] stroke patients[58] and patients with multiple sclerosis.[31] Increased sway of the centre of pressure and longer latency for muscle responses are also correlated with falls.[57,59,60] It is interesting to note that time in standing balance, investigated in five articles,[61–65] has been questioned as a fall predictor in elderly populations.[32] The Star Excursion Balance Test used by Hardy et al.[66] has been identified as a measure predictive of ankle injuries in basketball players.[67]

The majority of articles included in the review measured balance under static rather than dynamic conditions. This is of concern given the findings of several studies, which suggest that similar designs of AFO may improve aspects of balance under static conditions[62,68,69] but may compromise balance under dynamic conditions.[68,70]

In general, investigators did not clearly document the validity and reliability of specific outcome measures used in their research. As this is considered an integral part in determining the quality of research, the authors have attempted to locate literature related to the reliability and validity of each of the outcome measures presented. To identify studies of reliability and validity, a search was performed in the Medline database using the search terms reliability, validity, and repeatability together with the name of the specific outcome measure of interest. This search was not meant to serve as a comprehensive review of balance outcome measures but to give readers a general indication of the quality of the outcome measures used. Table 2 provides an overview of all outcome measures used to investigate balance in the reviewed articles and indicates whether reliability and validity have been established in previous literature. For convenience, outcome measures have been listed as either laboratory-based or clinical measures. Of particular concern are those measures that have been demonstrated as having poor reliability and/or validity (CoP displacement; CoP frequency) and those in which the authors were unable to identify research related to either reliability or validity.

In addition, learning effects have been associated with the use of several of the outcome measures listed in Table 2 . These include timed single-limb support with eyes closed,[33] the Sensory Organization Test,[71,72] the Limits of Stability Test,[73] and the BESS.[74] This suggests that repeated administration of the test is likely to result in balance improvements simply due to familiarization with the procedures. In the reviewed studies, most authors attempted to address learning effects by randomizing the order of intervention. However, other methods that could be used to address learning effects such as preintervention training, utilization of control groups, and accommodating for the learning effects in the analysis of results were rarely addressed.

SPORTS ORTHOSES

Of the 18 articles investigating orthoses for sporting applications, only five articles investigated balance in subjects with ankle instability. The major goal of orthotic management in this population is to provide mechanical support for the ankle joint complex. There is also some suggestion that circumferential pressure applied by orthoses will facilitate balance by improving proprioceptive input. However, none of the studies investigating patients with actual pathologies addressed this issue. Four of the five articles investigating patients with ankle instability indicated positive effects associated with the use of sports orthoses.[63,75–77] Two articles demonstrated reduced movement of the centre of pressure in the frontal plane with an orthosis,[75,77] one article indicated that single-limb stance duration was improved with orthotic use,[63] and the fourth article demonstrated improvements in a vertical stability index after a jumping task when subjects were fitted with orthoses.[76] Unfortunately, Fridén et al.[77] did not randomize the order of intervention throughout testing, and all subjects with ankle instability began the testing procedure with a nonorthosis condition. It is subsequently difficult to conclude whether the reported improvements in this study were a result of orthotic application or simply learning effects. Pintsaar et al.[78] reported no significant effects of orthotic use on the latency of muscular response or balance strategy (ankle or hip) used by subjects after a perturbation. No studies reported any negative effects on balance associated with the use of sports orthoses.

Three articles investigated both lace-up and semirigid orthotic designs,[63,75,76] whereas two articles investigated only semirigid designs. No evidence was found to suggest that performance on balance-related outcome measures was dependent on the design and construction of the sports orthosis.

Thirteen articles were reviewed in which sporting orthoses were tested on a normal healthy population. Healthy subjects are often fitted with orthoses as a prophylactic measure, and these studies aimed to assess 1) if there is any effect on balance associated with orthotic use and/or 2) if pressure applied by orthosis can enhance proprioceptive feedback for balance-related activities.

Results related to the effect of sports orthoses on balance were quite varied in healthy populations with six articles reporting no change in balance related to the use of sports orthoses,[61,64,66,79–81] two articles reporting negative effects,[24,82] and five articles reporting positive effects on balance.[18,83–86] Differences in the results do not seem to be related to the design of the sports orthosis but do seem to be dependent on the specific outcome measure chosen to evaluate balance. Analyses of variables related to the centre of pressure were performed in seven studies. Of these, two indicated that sports orthoses had no significant effect on balance and four indicated that balance was positively affected by the orthosis. It is interesting to note that in two of the studies reporting positive effects, change was only observed after fatigue.

The two studies reporting deterioration in balance when subjects were fitted with sports orthoses used outcome measures that were not investigated in any of the other studies. Bennell et al.[82] investigated ground reaction force variability, whereas Broglio et al. investigated balance using the BESS. There is some suggestion that data related to ground reaction force variability have superior reliability and sensitivity over centre of pressure measurements.[87] The BESS has been shown to have high reliability and validity[41] but, as acknowledged by the authors, is subject to learning effects, which the authors themselves suggest may have influenced their results.

Two articles specifically addressed the issue of orthotic use as a means of facilitating proprioception. Calmels et al.[83] claimed to measure the proprioceptive effect of wearing unilateral and bilateral orthoses. These researchers used force plate measurements during quiet standing as their main outcome measure. However, they failed to control for both learning effects and, more importantly, the effects that other components of balance (e.g., musculoskeletal, vision, vestibular) may have on balance control. As a result, their method was not appropriate as a specific measure of proprioception.

Papadopoulos et al.[79] investigated the relative effects of interface pressure on neuromuscular control. Based on their results, the group claimed that lace-up ankle orthoses have no significant effect on the peripheral skin receptors and that afferent signals were not influenced enough to affect balance. Outcome measures in this study were related to centre of pressure movement and velocity during single-stance and muscle activation sequences. Although the researchers did control for the effects that the visual system may have on balance by having subjects perform the test with eyes closed, they too failed to control for learning effects and did not, in our opinion, use tests that were sensitive enough to isolate the influence that proprioception alone may have on balance. Both Calmels et al. and Papadopoulos et al. investigated the effects of orthoses on a normal healthy population. It could be argued that any proprioceptive effects that an orthosis has would not be detected in a healthy population with normal neuromuscular function.

AMBULATORY ORTHOSES

Nineteen articles were categorized under the heading of ambulatory orthoses. Results among the reviewed articles were varied and include the following:

- Ten articles reporting positive results on balance-related outcome measures associated with the use of orthoses.
- Six articles reporting no significant difference on balance-related tasks when AFOs were compared with a shoe only or barefoot condition.[22,27,28,65,88]
- One article reporting positive effects associated with the use of rigid AFOs on static balance but negative effects for the same orthosis on dynamic balance.[68]
- One article reporting negative effects for rigid AFOs when compared with no orthosis for both static and dynamic balance activities and no difference for nonrigid AFOs.[70]
- One article indicating that the use of functional electrical stimulation resulted in superior balance when compared with use of an AFO.[89] This article made no comparison with a barefoot or shoe only condition.

After reviewing all articles involving ambulatory orthoses, it was clear that performance of certain balance-related outcome measures was dependent on the specific design of AFO. Of particular interest were findings related to rigid orthoses and their relative effects on static versus dynamic balance. Rigid AFOs were included in six articles.[25,27,28,65,68,70,89] Of these articles, two author groups chose to investigate both static and dynamic activities.[68,70] When investigating static balance, Burtner et al.[70] suggested that children with cerebral palsy had a decreased upright posture when fitted with rigid AFOs when compared with a no orthosis or a nonrigid orthosis condition. However, the authors failed to comment on the influence that inclusion of one prefabricated and one custom made orthosis may have had on the results. Further, they did not specify the tibia-to-floor angles obtained in the two AFO conditions, which seem to be quite different in their illustrative photograph. During a dynamic test, in which the children were subject to a sudden external perturbation, it was demonstrated that rigid AFOs caused a delay in recruitment of the gastrocnemius muscle and an inability to use an ankle strategy for balance recovery.[70] This was not observed in the nonrigid AFO condition or the no orthosis condition. Angular velocity of the knee and hip joints was also significantly higher in the rigid AFO condition, suggesting both an inability to use ankle strategy to rapidly respond to balance threats and the ability to substitute with an alternate balance strategy.[70]

Cattaneo et al.[68] also investigated static and dynamic balance tasks but focused on a sample of subjects with multiple sclerosis. In this article, negative effects were also reported in association with the use of rigid AFOs on dynamic balance tasks. When fitted with rigid AFOs, deterioration in performance was reported for both the timed walking test and the Perdiø test (a custom designed test for measuring dynamic balance). When using nonrigid AFOs, dynamic balance was significantly improved when compared with a rigid AFO condition. Interestingly, the rigid AFO resulted in significant improvements on the static balance tasks (CranioCorpo Graphy and Equiscale).

Unfortunately, four articles that included rigid AFOs did not control for the specific design of AFO worn by subjects.[25,27,28,89] Instead, these articles pooled data from subjects fitted with various types of orthoses, and as a result, the authors were unable to analyze any effects that AFO design may have had on their findings. Wesdock and Edge[65] investigated static balance in subjects fitted with rigid AFOs with and without shoe wedges and reported no significant differences in the duration of standing balance compared with a shoe only condition.

Six articles investigated leaf spring orthoses.[2,20,23,26,29,30] All reported positive results on at least one of the balance tests performed. Improved performance on the sensory organization test was reported by both Chen et al.[29] and Rao and Aruin,[30] suggesting a decreased latency between balance perturbation and musculoskeletal response. Improved performance on the limits of stability test were presented in two articles[2,23] whereas improved performance on the Timed up and Go test were reported in the remaining two articles.[20,26] In addition, improved performance was reported on the Berg Balance Scale,[23] weightbearing distribution during quiet standing,[2,23] and postural sway when standing on an unstable surface.[23] Five of these articles used stroke patients in their experimental design,[2,20,23,26,28] whereas the sixth article investigated patients with peripheral neuropathy.[30]

SMOs were investigated in four articles.[62,88,90,91] Two articles only investigated static balance.[62,88] Harris and Riffle[62] reported an improved duration of standing balance associated with orthotic use. Martin[90] and Pohl et al.[91] investigated both static and dynamic balance reporting improvements for both conditions.

QUALITY OF THE EVIDENCE

The quality of evidence was generally low to moderate in the reviewed articles for both sports and ambulatory orthoses. The majority used a before and after methodology (E5) in which measures were taken initially without orthotic intervention and then after application of each orthotic design. Although this method allows for subjects to serve as their own control, numerous authors failed to randomize the orthosis conditions, which meant that learning effects were not accounted for. One article was classified as a randomized controlled trial, whereas six articles were classified as controlled trials (E2)[20] in which control groups were compared with intervention groups. Unfortunately, in five of the six studies, the groups were not equal at baseline. One study was classified as interrupted time series design in which subjects were evaluated multiple times after receiving the intervention (E3),[65] and one study was classified as a single-subject experimental design (E4).[70]

Numerous articles compared two or more orthotic designs. No attempt was made in any of these articles to blind subjects or researchers from the specific design under investigation. This may have led to experimenter bias and placebo effects. Accommodation periods were also poorly used. In the majority of articles, subjects were not given any prolonged period of time before testing to accommodate to wearing the orthosis.

The number of subjects included in experimental trials was generally low with a mean of 19 in articles focusing on ambulatory orthoses and a mean of 25 in sports-related articles. Only three articles justified their sample size.[18,24,75] Given the low subject numbers, it was surprising that the majority of authors did not test to see whether their data were normally distributed before performing statistical analysis and that the majority chose to analyze their data using parametric statistics. In many cases, the authors feel that nonparametric tests would have been more appropriate.

Table 3 and Table 4 summarize the authors' confidence level related to the main outcome statements of this review. For each statement, the authors have listed relevant references, the study design classification, and their level of confidence in the outcome. In situations where numerous studies with a low level of evidence were available to support an outcome, the overall confidence was rated higher than that of the individual studies.

Statement	No. rated studies	Level of confidence in outcomes	References
Sports orthoses have either no effect or a positive effect on static balance in normal healthy populations	$6 \times E_5, 1 \times E_2$	Moderate	45,79,81,83–86
Sports orthoses facilitate dynamic balance in normal healthy populations	$5 \times E_5$	Moderate	18,61,64,66,84
Sports orthoses facilitate static balance in subjects with ankle instability	$3 \times E_2$	Low	63,75,77
Sports orthoses facilitate dynamic balance in subjects with ankle instability	$1 \times E_5$	Low	76
Performance on balance tasks is not influenced by the design of sports orthoses (lace-up and semirigid)	$2 \times E_2, 1 \times E_5$	Moderate	63,75,76

Table 3. Outcome statements for sports orthoses

Statement	No. rated studies	Level of confidence in outcomes	References
Rigid AFOs facilitate static balance	$1 \times E_5$	Low	__[68]
Rigid AFOs compromise dynamic balance	$1 \times E_2$, $1 \times E_5$	Moderate	__[68,70]
Non-rigid AFOs (excluding leaf spring designs) facilitate static balance	$1 \times E_5$	Low	__[68]
Non-rigid AFOs (excluding leaf spring designs) facilitate dynamic balance	$1 \times E_5$	Low	__[26,68]
Leaf spring AFOs facilitate static balance	$3 \times E_5$	High	__[2,23,30,68]
Leaf spring AFOs facilitate dynamic balance	$1 \times E_2$, $3 \times E_5$	High	__[2,20,23,29,30,68]
Supra malleolar orthoses facilitate static balance	$1 \times E_4$, $2 \times E_5$	Moderate	__[62,90,91]
Supra malleolar orthoses facilitate dynamic balance	$2 \times E_5$	Low	__[90,91]

AFOs, ankle-foot orthoses.

Table 4. Outcome statements for ambulatory orthoses for the patient populations included in the review

DISCUSSION

The aim of this systematic review was to evaluate the state of evidence related to the relative effects that AFOs have on static and dynamic balance. Given that AFOs are available in such a wide range of designs, articles were evaluated under two main categories: those addressing orthoses use for prevention of sporting injuries (including prophylactic use and prevention of further injury in subjects with ankle instability) and those articles addressing the use of AFOs for pathological conditions that affect ambulation. This discussion will address each of these categories independently.

SPORTS ORTHOSES

A major aim of articles addressing sports orthoses was to ensure that balance was not compromised when orthoses were used as a means of preventing injury in a normal healthy population or as a means of preventing further injury in a population with ankle instability. Combined results of the reviewed articles suggest that this is likely the case. No negative effects on balance-related outcome measures were identified as a result of wearing sports orthoses in a population with ankle instability (5 articles), and 11 of 13 articles investigating orthotic use in a normal population reported no effect or improved performance on balance tasks. However, it is important to acknowledge that two articles reported negative balance effects as a result of orthotic wear.[24,82] These two articles used outcome measures that had not been investigated in any of the other articles. A determination of which balance-related outcome measures correlate more closely with an increased incidence of sporting injury is needed before any conclusions can be drawn regarding the efficacy of these prophylactic orthoses.

It has been suggested that pressure applied to the ankle joint complex by sports orthoses can aid balance by facilitating proprioception. Two of the reviewed articles claimed to address this issue; however, methodological flaws in both articles do not allow us to draw any conclusions related to the use of sports orthoses and improved proprioceptive feedback. It is recommended that future studies combine outcome measures related to static and dynamic balance together with measures that specifically isolate joint proprioception. The authors also believe that it is more appropriate in such studies to use subjects with pathological conditions of the ankle rather than normal subjects.

Lace-up sports orthoses and semirigid sports orthoses were most often investigated. Based on the combined results of the reviewed studies, it can be concluded that the level of confidence to suggest that any one design of sports orthosis improved or compromised balance to a greater extent than the other is considered moderate.

AMBULATORY ORTHOSES

Although orthotic design did not seem to affect balance in sports-related papers, this was not the case for ambulatory orthoses. Of particular interest were rigid orthoses that resulted in either no change or improvement of performance on static balance tests but deterioration in performance under dynamic test conditions. This result is not surprising given that dynamic balance requires a degree of ankle joint motion that is intentionally inhibited in rigid orthoses. It does, however, raise the question of when, or for which pathological conditions, rigid AFOs may be appropriate. In the reviewed literature, negative results on dynamic balance tasks were demonstrated in subjects with cerebral palsy[70] and multiple sclerosis.[68] It is worthy of note that both groups were reported to have weak to moderate strength in their ankle musculature at the time of testing. To fully understand how AFOs affect balance, additional research is required to determine the influence they may have on static and dynamic balance in populations with no active ankle control.

Results from several studies suggest that leaf spring orthoses may have positive effects on balance in adults with stroke-induced hemiplegia. The level of confidence in findings supporting the use of leaf spring AFOs was considered high. Results related to the use of SMOs suggested with a moderate level of confidence that they serve to enhance balance for children with spastic diplegic or quadriplegic cerebral palsy. Once again these results cannot be generalized across pathological conditions, and additional research is required to ascertain whether balance can be improved in other populations using these designs.

GENERAL COMMENTS

It is important to recognize that this review focused only on studies that used measures of balance as outcome measures. This review did not take into consideration other variables that may be affected by the use of an AFO (e.g., gait variables). Balance is just one factor that should be considered by clinicians when prescribing an AFO, and findings of this review must be weighed against other potential benefits or disadvantages associated with orthotic use. In sports-related studies, this could include the frequency of injury or sporting performance. In studies involving ambulatory orthoses, it could include variables such as gait parameters, contracture management and prevention, quality of life measures, and ability to perform various activities of daily living.

A very wide range of balance measures were used in the studies represented in this review (30 different measures). The wide variety of measures makes comparison across studies particularly difficult and highlights the importance of determining which outcomes are most relevant. A major difference when comparing the sophistication of the outcome measures is the ability to distinguish between the specific components involved in maintaining balance (somatosensory, visual, and vestibular). It is important to recognize that whether the goal of research is to identify the underlying mechanism by which AFOs influence balance, and it is necessary to use a series of outcome measures that differentiate between these specific components. However, if the underlying goal is simply to investigate general improvement or deterioration of balance associated with AFO wear, then a clinical test may suffice as long as reliability and validity have been established.

The descriptions of AFO design presented in numerous articles included in this review were quite poor, making it particularly difficult to determine the intended function of the device. This issue has been raised previously.[92,93] To standardize descriptions of AFO, the authors recommend that future publications use the standards outlined in the International Society for Prosthetics and Orthotics report related to developments in healthcare for cerebral palsy.[92]

LIMITATIONS OF THE REVIEW

One potential source of bias is that both authors of this review are certified orthotists in Sweden. N.R. completed her undergraduate and postgraduate education in Australia, and S.R. completed his undergraduate and postgraduate education in Sweden. The authors have been working at the same institution together for 5 years, and it is likely that their working environment has shaped their opinion regarding the methodological quality of the articles included in this review. Neither of the authors has been involved in any of the publications under review.

This review focused only on balance-related outcome measures and did not examine other potentially beneficial effects that AFOs may have. It is possible that although certain AFOs may have no influence, or even a negative effect on balance related measures, they may significantly improve other variables not included within the scope of this review. This includes temporospatial, kinematic, and kinetic parameters of gait, energetics, spasticity, contractures, and measures of proprioception and pain.

In addition, the inclusion criteria restricted the review to only English language sources. Because of the lack of wellcontrolled studies and the resulting low to moderate level of the available evidence, caution should be exercised when generalizing from the conclusions in this report.

RECOMMENDATIONS FOR FUTURE RESEARCH

After a comprehensive review of all 37 articles, numerous methodological flaws that repeatedly appear in the published literature were identified. Numerous areas were also identified as requiring additional research to establish a complete picture of the relative effects that AFOs have on balance. When considering research methods for future studies, it is recommended that authors include both static and dynamic measures of balance as dependent variables. The authors also wish to stress the importance of using measures that are known to be both valid and reliable. In terms of study design, there is an obvious need for high-quality, randomized clinical trials. Future studies should aim at fulfilling this need by including control and intervention groups that are equal at baseline and sufficient in number to ensure appropriate statistical power.

Specific areas that require attention from the research community include studies into the relative effects AFOs have on proprioception, the relationship between proprioception and balance, and further research in relative effects of AFO design on balance. It is important to recognize that performance on balance-related outcome measures may be dependent not only on the orthotic design but also on the subject group selected for investigation. To generate appropriate prescription criteria, it is necessary that a wide variety of patient groups are investigated.

CONCLUSION

The relative effects of AFOs on balance were the key focus of this systematic review. Thirty-seven articles were identified for inclusion and were reviewed by the two authors. Although the level of evidence of articles was generally low to moderate, several clinically relevant conclusions can be drawn based on the combined results of all studies.

Combined results from studies investigating sports orthoses suggest that these devices are unlikely to compromise balance when used as a prophylactic measure in normal populations. When used as a means of preventing further injury in populations with ankle instability, they may even offer positive effects on various balance-related outcome measures. No evidence exists to suggest that the specific design of sports orthoses tested to date (lace-up and semirigid) has any effect on balance-related outcomes.

Results of studies investigating ambulatory AFOs provide some evidence to suggest that balance outcomes are dependent on the specific design of the device. Although rigid designs seem to be beneficial in static balance tasks, more flexible designs seem to be superior under dynamic balance conditions. It is important to recognize that the reviewed studies were limited to certain patient populations with stroke patients and subjects with cerebral palsy most often represented. Additional research is required to determine whether these findings can be generalized to other patient populations.

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