



## Efficacy of different techniques of AFO construction for hemiplegia patients: A systematic review

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### Abstract

**Background:** Ankle foot orthoses (AFOs) are frequently prescribed to improve gait deviation and normalize walking pattern in patients with drop foot hemiplegia disorder. This study was to review the efficacy of different techniques of AFO construction and biomechanics parameters of AFOs. Furthermore, this study aimed to provide a guideline for researchers in detail and help them choose a sufficient measurement instrument.

**Methods:** Information sources included MEDLINE, CINAHL, Scopus, PubMed, and the Full Cochrane Library up to December 25, 2015. The inclusion criteria include: (1) type and method of controlled clinical trial studies; (2) age of hemiplegia groups (3); AFOs as an intervention; and (4) kinetic and kinematic parameters, and energy expenditure as an intervention of gait performance.

**Results:** Considering eligibility criteria such as study design, setting, time frame and Language 9 papers with Pedro scores of 5 to 8 for methodological quality were included in the review.

**Conclusion:** The findings of this review can help to develop guidelines for the best AFO reporting as an intervention and to prevent vagueness of results in the different types of AFOs.

**Keywords:** Adolescent, Hemiplegia, Child, Gait, Orthoses, Brace, Systematic review

**Conflicts of Interest:** None declared

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### Introduction

Ankle foot orthoses (AFOs) are the most prescribed interventions to improve gait deviation in patients with drop foot hemiplegia disorder. In this disorder, foot clearance deteriorates during the swing phase leads to poor foot placement at initial contact (1-4). Several studies have investigated the efficacy of AFOs as interventions for improving the kinematic and kinetic of gait in drop foot hemiplegia patients(1,3-4). However, in most of these studies, an ambiguity is seen in selecting mechanical ele-

ments (3-4). Besides, in some studies, technical efficacy of AFOs in fabrication and test strategy were neither mentioned nor had enough clarity (1). Also, much controversy exists about the AFOs' intervention reliability, validity, clinically relevancy, and outcome measurement which would affect the confidence in prescribing, utilizing and generalizing AFOs (2). As an intervention with sufficient details in trial reports, evaluation of quality of AFOs is highly important (3-5). Although general guidelines exist

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#### ↑What is “already known” in this topic:

Ankle foot orthosis (AFO) is frequently used to improve gait deviations in patients with hemiplegia. AFOs prevent foot drop in the swing phase and promote heel strike in the early stance phase of gait.

#### →What this article adds:

A variety of studies have reported the AFO is an effective tool for improving the gait pattern of hemiplegia patients. This study provided some guidelines to robustly report AFO interventions, mechanical characteristic of AFOs, and efficacy of AFOs' construction techniques, testing strategies and the outcomes.

for AFO application as an intervention in clinical, randomized and non-randomized trials (6-9), few studies have dealt with the efficacy of AFOs' intervention guidelines (1-4). Therefore we were set to drive an acceptable, specific, and efficient guideline from the body of the literature. Variable efficacy, which was used in this study, was provided from the body of orthotic literature (3-5).

This study was the first review to specifically concentrate on efficacy reported by AFO intervention studies on hemiplegia and to focus on participants' information, AFOs' interventions, mechanical characteristic of AFOs, and construction and testing strategy and outcomes. Thus, we were set to develop an indicator for assessing and reporting AFOs' detail from the body of literature. The findings of this review should provide a practical and applicable guideline for reporting research results. The proposed guideline should also improve the reporting quality of future AFOs related evidence-based papers and RCT studies.

## Methods

The Cochrane review guideline was used for a comprehensive search strategy (10). Then, electronic databases including MEDLINE, CINAHL, SCOPUS, PubMed, and the full Cochrane Library were searched through for retrieving eligible research. Databases were searched for English articles with no prior exclusions, restrictions, or limitation. The reference list from the relevant identified papers was also searched manually, and gray literatures were not considered. Initially, all English publications between 2000 and 2015 were considered for inclusion; then, following the abstracts, full-text versions of papers were used for further evaluation.

## Inclusion criteria

AFOs' related studies in hemiplegia persons to study resist motion in spastic or paretic drop foot hemiplegia or assist ankle movement by applying force through a three-point pressure system were selected. Only the randomization related participant (RCT) and experimental works were included, and systematic reviews, case studies, and narrative reviews were excluded.

## Data extraction

The title and abstract of identified studies were assessed by 3 reviewers, (EP), (AB), and (BF), who were blinded

to authors, affiliations, and the publishing journal. At first, the title and abstract of each study was reviewed, then, full text papers were separately evaluated by 3 review team members.

For inclusion or exclusion, each paper was rated using a modified version of the PEDro rating scale with 11 items, assessing the internal validity (Appendix 1) (12). All items scored from one to ten; the first item was related to external validity. Then, all the initially excluded papers were rechecked by the second reviewer (BF) to ensure that they have not been excluded by chance.

Then a full-text reading was planned and again the unfitted articles excluded. To minimize rater error in each criterion, we followed a specific standardized guideline so that up to a satisfactory point.

Hand searching of reference lists were conducted by the same reviewers. According the literature (3-5, 13, 14), ISPO consensus conference documents (1, 15), systematic reviews and checklist guidelines (16), as well as quality checklists previously used in other systematic reviews (17, 18), there was a need for a guideline for technical and detail assessment of AFO. Since our study needed a special quality checklist to provide a systematic assessment of evidence quality a new checklist was designed and adopted using a systematic review of the literature (Table 1). According to the International Classification of Functioning (ICF), there are three main themes to the checklist:

1) Participant information, including denoting type of disease, patients' age, lower limb passive joint range of motion (ROM) and the description of a deformity within the lower limb regarding a pattern of lower limb motion.

2) Mechanical characteristic of AFO and construction, including reporting the aim of the orthotic, type of articulation, range of motion permitting, preventing, or assisting, initial angle of AFO ankle, toe plate length, material type and thickness and trim line, AFO tuning and modification, final angle of shank-to-vertical AFO as angle between the lower leg and vertical while standing in the AFO (19) and custom-made or prefabricated design.

3) Testing strategy, including reporting of the control and test conditions, and details regarding randomization and adaptation and comparing AFO with other modalities. The data extraction and quality assessment to check content and reliability were piloted by both reviewers (EP, BF).

Finally, quality assessment of the quantitative studies were conducted using the EPHPP quality assessment tool

Table 1. Quality assessment of the quantitative studies using the EPHPP quality assessment tool

Study	Study design	Global quality rating	Study design	Protection against selection bias	Control for potential confounders	Blinding <sup>a</sup>	Reliability and validity of data collection methods	Retention	PEDro score
Bucken et al 2004 (24)	RCT	Strong	Strong	Strong	Strong	Moderate	Moderate	Strong	8/10
Sienko 2002 (37)	RCT	Strong	Strong	Moderate	Strong	Moderate	Moderate	Weak	7/10
Thompson 2002 (25)	RCT	Strong	Moderate	Strong	Moderate	Weak	Moderate	weak	6/10
Desloovere/ Vangestel 2008 (3)	RCT	Moderate	Moderate	Weak	Weak	Weak	Moderate	Weak	5/10
Brehm, Merel-Anne 2008 (48)	RCT	Moderate	Moderate	Weak	Moderate	weak	Moderate	Weak	5/10
Vangestel 2008 (31)	RCT	Moderate	Moderate	Weak	Weak	Moderate	Moderate	Moderate	6/10

Table 1. Ctd

Study	Study design	Global quality rating	Study design	Protection against selection bias	Control for potential confounders	Blinding <sup>a</sup>	Reliability and validity of data collection methods	Retention	PEDro score
Bregman, Daa R (1)	RCT	Strong	Strong	Strong	Strong	Moderate	Moderate	Moderate	7/10
Cakar E 2010 (51)	RCT	Weak	Moderate	Weak	Weak	Moderate	Weak	Moderate	5/10
Kerkum 2014 (52)	RCT	Strong	Moderate	Moderate	Moderate	Moderate	Strong	Moderate	7/10

(Table 1).

## Results

The screening phase yielded 178 abstracts, and 34 articles and hand searching led to 189 papers (Fig. 1). After a full-text review of 189 titles 41 articles were found to be eligible that were included in this review. Ultimately, 9 studies were included for qualitative analysis and evidence synthesis.

Table 2 depicts the demographic characteristics of participants, sample size of the study, clinical diagnosis, type of interventions, characteristic of control group, study design and preliminary outcome measurement. Most articles evaluated kinetic or kinematic of the gait whereas walking on a level surface. Others evaluated balance or energy consumption.

Table 3 gives an outline of the data extraction and quality results over all studies.

### Mechanical characteristic of AFOs and construction

Mechanical approach was applied to confirm the effectiveness of AFOs interventions and to pursue gait measurements at the level of body functions and structures (3, 6–10, 24, 30–34). Assessment of AFOs interventions at the level of kinematics and kinetics at the ankle joint and

proximal joints may be considered as a tool for checking the quality of the AFO intervention itself. This reveals the primitive effect of an AFO on the ankle and foot function (24). Outcome measures from gait analysis, either broad indexes or particular joint measures, represent a shift towards normality and can thus be noted relevant to confirm effectiveness of AFO interventions (30–34). At last, nine studies clearly stated the AFOs ankle angle and the position of leg during casting or Scanning process, which were synthesized in this study.

AFOs' modification caused significant positive biomechanical effects at drop foot hemiplegia studies. Materials and other details related to the thickness or process of manufacturing were mentioned in this paper. Custom-made devices were most commonly tested (Table 3), however, in some articles the process of fabricating was ambiguous or not mentioned. AFO fitting of the patients was not mentioned in reviewed articles. A follow-up measure was not conducted in any reviewed paper in this study.

### Testing strategy and outcome measure

Most studies used a randomized clinical trial (Table 4) than non-random study. Remaining studies either did not report type of their study or it seems to be ambiguous. Weaning time was also considered as a part of the strategy

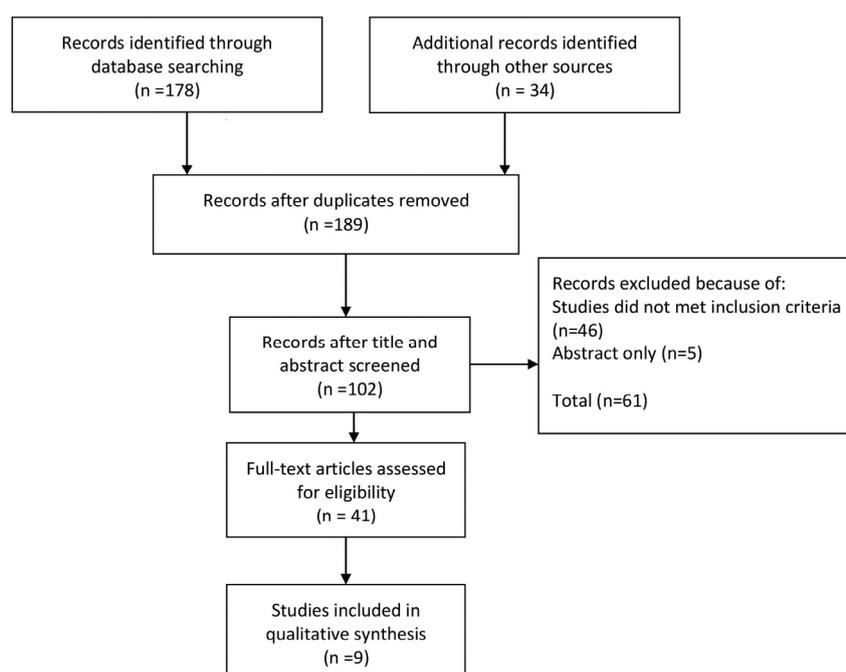


Fig. 1. Flow of study selection

Table 2. Details of the included studies

Author	Sample size	Participant characteristics	Intervention(s) vs control condition	Procedure	Outcome measures	Result and conclusion
Buckon et al, 2001 (24)	16 spastic diplegia 10 males 6 females; mean age 8 y 4 M; range 4 years 4 M- 11 y 6 M 4 children were classified at level I of the Gross Motor Function Classification System, the remaining 12 were at level II	posterior leaf spring (PLS), + hinged ankle-foot orthosis + solid ankle-foot orthosis Vs: barefoot (b f).	There are four visits for Each child: an standard assessment, after 3 months of no AFO wear, and an evaluation at the end of each AFO three-month wearing measured by gait analysis	Three-dimensional kinematic and kinetic gait data at the pelvis, hip, knee, and ankle , energy expenditure, and functional motor skills(Upper extremity function, Gross motor function and performance)	AFO use, regardless of configuration, did not significantly alter pelvic and hip kinematics and/or kinetics from the BF condition. At the knee there was no significant kinematic change. one kinetic variable (peak knee extensor moment in early stance) was significantly (p=0.007) increased in the HAFO configuration compared with BF. All AFO configurations significantly altered ankle kinematics during the stance and swing phases. All of the AFO configurations significantly increased step (p<0.005) and stride length (p<0.006) compared with BF, while significantly decreasing cadence (p<0.0005). Energy cost (mL.O2/kg/m) was significantly decreased in self-selected and fast walking in all AFO configurations compared with baseline (p<0.003).	
Susan Sienko Thomas et al 2002 (37)	19 19 children with spastic hemiplegia 11 males+ 8 females ,mean age : 9 + 3 years (range 6 – 15 years and mean weight : 34.7kg	barefoot and hinged, posterior leaf spring (PLS) and solid AFO	Children were evaluated barefoot (first 3 months) and with a hinged PLS and solid AFO (each AFO for 3 months) during stair ascent and descent. a motion analysis system was used to measure kinematics.	Kinematic data for stair locomotion	Kinematics: The hinged AFO allowed significantly greater dorsiflexion (16°) during stance than barefoot (10°, P = 0.0007) and the solid AFO (9°, P = 0.0002) configuration. Dorsiflexion during swing was significantly greater for the hinged (14°) and PLS (10°) AFOs in comparison to barefoot Conclusion: AFOs do not inhibit the ability of the child with spastic hemiplegia to ascend and descend stairs. All AFOs improved the foot contact position during stair ascent.	
Thompson (25)	18 hemiplegia, 8 females and 10 males , mean age 8 y 5 m (range 5 y 8 m to 11 y) Patients usually walk wearing a rigid polypropylene AFO	Custom made rigid AFO	Children evaluated by gait analysis using a six camera Vicon and musculoskeletal modelling using specially designed software( first bare foot Then with AFO)	temporal/spatial parameters knee and ankle kinematics hamstring length	With AFO: There were significant increases in cadence, step length, and walking velocity with significant improvements in knee kinematics. At the ankle the expected decrease in ankle motion and significantly improved ankle dorsiflexion at initial contact and stance were observed Conclusion: pathological gait patterns in CP are reflected in measurements of maximum muscle length during the gait cycle.	
Desloovere/ 2008 (3)	15 children diagnosed with hemiplegia, mean age: 5.86 years (1.76), 8 children had right, and 7 children had left side involvement.	Common PLS+ Dual Carbon Fiber Spring AFO (CFO)	Walking of Children tested in 4 conditions at random order: barefoot, shoes only , with PLS and CFO combined with shoes Kinematic evaluation was done using an eight-camera VICON system	Spatio-temporal parameters, Kinematics, kinetics at ankle, knee, hip joint	cadence significantly improved in shoes compared to barefoot. At ankle level: significant increased range of motion and angular velocity during push-off. Increased knee shock absorption, knee flexion in swing and maximal knee extension moment in stance. Finally, mean coronal hip angle in swing, mean pelvic obliquity, and maximal hip power absorption in stance were significantly increased in shoes when compared to barefoot (P < 0.01). Walking velocity and step length increased in both orthotic conditions when compared to barefoot conclusion, both orthoses successfully improved gait patterns, but push-off at the ankle significantly improved when the CFO was compared to the PLS	

for new or unfamiliar devices. Most studies clearly utilized the control group, the barefoot condition was the most common type of control followed by wearing shoes and both barefoot and with shoes.

This review identified full papers which evaluated the effect of AFOs on the different range of outcome measures in hemiplegia patients with considerable varieties in various study strategies. In many cases this posed

limits for assessment of intervention quality and deteriorated the findings.

#### Type of measurement

Computerized 3D gait analysis with or without force plate were used as a useful method of evaluating gait in hemiplegic patients with AFO (12). Kinetic and kinematic data derived from these studies may be considered as a

Table 2. Ctd

Brehm et al 2008 (48)	181	110 boys and 71 girls with spastic cerebral palsy: mean age 9 years (range 4.6–18.4) 23 hemiplegia, 103 diplegia, 55 quadriplegia	Barefoot+ shoe+ Solid AFO +shoe PLS	oxygen consumption measured by a breath-by-breath gas-analysis system biomechanical analysis of gait, was done along a 10-m walkway.	Oxygen consumption Speed and GGI (activity)	Speed improved significantly by 8.2% with solid AFO ( $P < 0.001$ ). Cost of walking was 6% lower with AFO ( $P = 0.007$ ) (a significant decrease in cost of walking for PLS walking (8%), whereas for solid AFO, walking remained unchanged). The GGI remained unchanged ( $P = 0.607$ ). Changes in minimum knee flexion angle in stance phase and in terminal swing ( $P = 0.013$ and $P = 0.022$ , respectively) Conclusion: AFO significantly decreased the energy cost of walking of quadriplegic children with CP, compared with barefoot walking, but remained unchanged with hemiplegic and diplegic CP The Upper Limb Coordination ( $p < 0.003$ ) and Upper-Limb Speed and Dexterity ( $p < 0.016$ ) subtests were significantly improved in all AFO configurations compared with BF, with no significant difference between AFO configurations Conclusion :AFO use enhances the functional abilities of most children with spastic diplegia
Van Gestel et al 2008 (31)	36	Children with hemiplegia: 15 boys, 22 girls, mean age: 8.5 2.8 years (range 4–10 years) GMFCS Level: I and II	PLS CFO (Dual Carbon Fiber Spring AFO) Orteams (orthoses with the dorsal part containing 11 sleeves) Bare-foot	Walking of Children measured and compared by gait analysis, including 3- D kinematics and kinetics in 4 conditions: barefoot, and with 3 types of AFOs	Stride temporal Kinematics, and lower limb moment (body function and structure) Gait speed GMFCS (activity)	Cadence significantly decreased and step length and walking velocity significantly increased with orthoses (all $P = 0.001$ ). Knee range of motion during shock absorption, swing kinematics, and most knee kinetics also significantly changed ( $P = 0.001–0.004$ ). About half of the hip kinematics showed a significant effect of orthoses and all hip moment and power were significantly increased ( $P = 0.001–0.006$ ). Only the CFO could significantly improve ankle dorsiflexion at loading response vs the barefoot condition ( $P = 0.007$ ) Conclusion: although the PLS ensured the highest correction at the ankle around initial contact, the CFO created a significantly higher maximal hip flexion moment in stance
Bregman 2008 (1)	7	4 stroke patients (1 right side, 3 left side) 3 MS patients (2 right side, 1 left side)	Three AFOs were of the type Dynafo (Maramed Orthopaedic Systems, Hialeah, FL, USA), and four AFOs were of the type 298 D. J. J. Bregman et al. Orteam	Patients walked with shoes only, and with both shoes and AFO, 3-D gait analysis was performed. The balance without AFO was evaluated using the Berg Balance scale, the spasticity of the gastrocnemius and soleus was evaluated using the Spasticity Test (SPAT). energy consumption was measured.	Energy Cost of walking Ankle Kinematics ankle kinetics	There was a significant decrease of 12.1% (+ 10.6) in EC of walking when patients walked with the AFO. The AFO changed the ankle joint kinematics in the benefit group. The AFO did not change the ankle joint moment Conclusion: he authors found a clear link between the mechanical effect and the energetic functional effects of the AFO
Cakar 2010 (51)	25	Spastic hemiparetic post stroke patients 17 male 8 female Mean age: 60.52 (range: 35–80)	Prefabricated PLS with footwear	Patients were instructed to regularly use PLS with footwear. Balance and fall risk were evaluated a week later	Berg balance scale Postural and fall risk test of BIO-DEX balance system	No statistically significant change in any of the PST scores by use of pls Conclusion: prefabricated PLS improved balance and reduced fall risk
Kerkum 2015 (52)	15	Spastic CP children 11 boys 4 girls aged between 6 and 14 years old	Shoe only vs ventral shell spring-hinged AFO (three configuration stiffness)	In order to acclimatization, each vAFO stiffness configuration was worn for a period of four weeks, after which efficacy of that vAFO was assessed using 3d gait analysis and a 6-minute walk test to measure walking energy cost	Walking energy cost daily activity, gait biomechanics	Speed was significantly lower while walking with vAFOs decreased the knee flexion angle at contralateral toe-off, midstance, and at timing of KEpk. Also the internal knee flexion-extension moment at midstance and at timing of KEpk were significantly improved by all vAFOs. A significant reduction was found for the vAFO compared to walking shoes-only

useful predictor of efficiency of AFO. Beside the gait analysis, energy consumption as a method for evaluating effective output of gait was used in some studies. For detailed study of mechanical property of AFO BRUCE device was used as an acceptable method. Ethical approval

as necessary part of each study was considered in all papers included the current study (20).

## Discussion

In this systematic review, nine full papers using AFO in

Table 3. Mechanical characteristic of AFO and construction

Author	AFO movement	AFO angle	Toe plate	Material	Type of AFO	Type of fabrication	Alignment
Buckon et al., 2001 (24)	√	√	Full length	√	SAFO	Custom	√
Susan Sienko Thomas et al 2002 (37)	√	√	¼full	√	PLS	Custom	√
Thompson (25)	√	-	Full	-	SAFO	Custom	√
Desloovere 2008 (3)	√	-	Full	-	SAFO	Custom	√
Brehm et al., 2008 (48)	-	-	Full	-	PLS	-	-
Van Gestel et al., 2008 (31)	√	-	Full	√	PLS	Prefab.	-
Bregman 2008 (1)	√	√	Full	√	DAFO	Prefab.	-
Cakar 2010 (51)	√	√	Full	√	PLS	Prefab.	-
Kerkum 2015 (52)	√	√	Full	√	hingAFO	Custom	√

Table 4. Testing strategy and outcome measure

Author	Study design	Orthotic aim	Method	Outcome Measure
Buckon et al., 2001 (24)	Prospect	-	Clinical trial	Kinematic/energy cost
Susan Sienko Thomas et al 2002 (37)	Prospect	Ambiguous	Clinical trial	Energy Kinematic Kinematic
Thompson (25)	Prospect	Clear	Clinical trial	Kinematic/kinetic
Desloovere 2008 (3)	Prospect	Clear	Clinical trial	Kinematic/kinetic
Brehm et al., 2008 (48)	Prospect	Clear	Clinical trial	Energy cost / walking efficacy
Van Gestel et al., 2008 (31)	Prospect	Clear	Clinical trial	Kinematic/kinetic
Bregman 2008 (1)	Prospect	Clear	Clinical trial	Functional effect /mechanical properties
Cakar 2010 (51)	Prospect	Clear	Clinical trial	Balance/postural stability
Kerkum 2015 (52)	prospect	Clear	Clinical trial	Mechanical properties

drop foot hemiplegia were analyzed. In agreement with previous reviews (4, 5) there was considerable variety in the quality of efficiency details and techniques of AFOs (1-4) that posed limits to efficiency evaluation and maintaining confidence of findings. This variability and incomplete reporting of data further reduces the usability of the finding in meta-analysis (4, 5).

In this review we tried to explore each phases of RCTs (21) to assess the efficacy of design and fabrication of AFOs in drop foot hemiplegia. Thus, probable benefits of any priority in clinicians' decision making may lead to improve the prescription (22).

The level of activity was considered as the most relevant outcome parameter of the ankle (21, 23) which quantifies walking ability and the level of the need of a patient for the potential benefit of orthotic treatment. Walking performance, i.e., walking in daily life, Stability (safety), walking speed, walking economy (PCI, EC and oxygen uptake) and dynamic stability (25-27, 24, 30, 31) fairly determined the different aspect of patients' problems and needs (21-23).

Some studies were subdivided their participants according to level of pelagic condition, gait pattern, and differences in outcomes between the different types of AFO (23, 24, 30, 31). As a result, differences in outcome measures and type of AFOs used in drop foot hemiplegia have obliged researchers to concentrate on participant groups, which is a degree of homogeneity regarding gait pattern. Also, these differences sometimes led to variety in sub-dividing including age of participants and type and severity of the disorder (27). For instance, we found some studies which concentrated either on different groups according to gait pattern or particular gait abnormalities (21, 23, 24, 25, 28).

Several other studies ensured homogeneity by describing knee and ankle posture either with (21, 23) (24, 25, 28) (29-32) or without reference to published gait classification systems (39). Several other studies used knee and ankle posture to subdivide participants' gait classification systems (39) with and without references (38).

Another source of homogeneity is the design and construction of the AFOs that as an essential part of hemiplegic research should be clarified (33). It showed differences between AFOs and diversity in spatiotemporal parameters (33-35), ankle and knee and hip kinematics (3, 24, 34-36) as outcomes in straight line walking and stair ascent and descent as well as doing some reach tasks (37, 23).

It seems that AFOs with a positive influence to align the joints of drop foot hemiplegia lead to improve kinematic variable such as in cadence and gait velocity (23).

Regarding adaptation time with AFOs, a tendency toward improvement in kinematic parameters like speed of walking and cadence was found (38-40). All types of AFOs led to significant improvement in walking speed in comparison to control groups. However, different studies were reported different results for cadence with and without AFOs, and majority of studies reported increase in speed of walking. As cadence is the number of steps per certain time, some patients showed increase in speed of walking without any changes in steps per minute (1-4).

The AFO alignment is described by the AFO ankle angle in respect to leg which considered in casting process. In such cases the ankle dorsiflexion only occurred with knee extension (14, 19, 32, 38).

Combination of the AFO with shoes may alter the angle between shank and foot which was deteriorated the alignment of the AFOs relative to vertical angle especially while difference was existed between the height of the heel and forefoot (19, 32, 38, 39, 40). Differences in shank-to-vertical angle because of shoes have been showed to increase the efficacy of the alignment of the ground reaction force (GRF) during standing. Modification of this angle could be due to improving of GRF orientation during walking (14, 19, 32, 40-45).

As it is revealed from evidence individual alignment and modifying of every AFO may help preventing inappropriate SVA angle to obtain optimal outcome (19). However, AFO modification was not a new concept but recently it seems to be considerable as a part of improving the function of hemiplegia (3, 31, 32, 39, 40). In order to overcome this limitation, the shank-to-vertical angle is described as criteria for the alignment of the AFO and footwear- orthosis should be considered in casting process (3, 31, 32, 39, 46-48).

For better function, the foot section stiffness of the AFOs in addition of the shoes frequently provides the firm lever arm. As a result, shoes as a part of the orthotic intervention determined the neutral angle of the AFO and the inclination of the tibia (33, 48). This combination is obtained by adding the heel height of the shoes to arrive at the optimal tibia inclination (47, 49). This inclination angle was achieved by measuring net moment of the hip and knee joints (3, 31, 32, 39, 47, 49). To our knowledge, only one study has examined the effect of different AFO toe-plate lengths in hemiplegic post-stroke adults (38). The result of this study reported significant differences in the amount of dorsiflexion at the stance phase.

Some studies in this review clearly reported that AFO was used to resist the ankle foot unwanted movement, depending on structure and mechanical properties such as trim line position and material properties. Vast majority of material properties used in fabrication of the AFOs may also influence the flexibility of these devices and the mobility of the ankle and metatarsophalangeal joints (38). Despite suitable examples (21, 24, 35, 41, 42), detailed technical points in AFO design were missed in some studies (43, 44,47,49). Using newly designed method for measuring AFOs stiffness with approved reliability and clinical applicability (48, 50) has recently been described.

To enhance AFO intervention results, they must be more accurately assessed regarding the design. Further work should be done on the movements prevented, assisted and permitted by the AFO design like mechanical articulation or special trim line, toe plate form and length and flexibility (21, 24, 35, 41, 42), materials and method of fabrication, AFO ankle angling combination with SVA angle with shoes, type of shoes worn and details of any modifying in AFOs.

Clear reporting of technical aspect of AFOs in every study helps to understand the variables that may affect AFOs as an intervention (44-45). In current study only a randomized trial paper was chosen as it eliminated bias resulting from the order of testing (45) and is particularly important in orthotic research as there are usually two or more conditions being compared over repeated trials of tasks such as walking.

Nonrandomized order of testing introduces the risk of fatigue in the tasks performed last and not used as a usual method in orthotic intervention, except in retrospective analysis.

All reviewed studies were performed in barefoot or shod with and without AFOs. We included both barefoot and shod conditions. According to these studies, shoes alone could have either a negative or positive effect on gait pa-

rameters in the section of SVA (46). Weaning time is needed to adapt with an unfamiliar device which ensuring researcher that the effects of the device accurately represent daily use. Most of these studies were followed at least one week and only one study was conducted in less than one day (36, 42).

#### Future research

We tried to emphasize on improving the quality of the body of literature. Furthermore, we tried to present a systematic and detailed approach for reporting the participant's demographics, the AFO intervention and testing strategies. This review has raised several questions and provided their answers. For example, what is the most appropriate control condition for comparison with an AFO intervention? What is the minimum weaning required for an unfamiliar device? Do small differences in AFO design; stiffness and alignment have a significant effect on AFO effectiveness? Answering these questions might facilitate comparison of already published studies. These are in line with suggestions arising from the recent International Society for Prosthetics and Orthotics (ISPO) consensus conferences on the orthotic management of on CP (47) and stroke (15). Finally, future studies should aim to identify the most relevant biomechanical parameters for gait analysis in drop foot hemiplegia for better guideline designing.

#### Limitations

Although this study provides some guideline for AFO prescription, there are still a lot of unraised questions about the different aspects of the best AFO design and the duration of AFO usage.

#### Conclusion

This study tried to construct a robust guideline for reporting the details of AFO as an intervention (7). The guideline should also be helpful for future investigations in other areas and may improve the synthesis of quantitative research.

#### Conflict of Interests

The authors declare that they have no competing interests.

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*Appendix 1. Scoring items of the PEDro scale*

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Items of the PEDro scale

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## External validity

1 The eligibility criteria were specified.

## Internal and statistical validity

2 The subjects were randomly allocated to groups.

3 The allocation was concealed.

4 The groups were similar at baseline on most important prognostic indicators.

5 There was a blinding of all subjects.

6 There was blinding of all therapists who administered the therapy.

7 There was blinding of all assessors who measured at least one key outcome.

8 Measurements of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups.

9 All subjects from whom outcome measures were available received the treatment or control condition as allocated; where this was not the case, data for at least one key outcome were analysed by "intention to treat".

10 The results of between-group statistical comparisons are reported for at least one key outcome.

11 The study provides both point measurements and measurements of variability for at least one key outcome.

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