Systematic Review

JOURNAL OF CHILDREN'S ORTHOPAEDICS

Do research papers provide enough information on design and material used in ankle foot orthoses for children with cerebral palsy? A systematic review

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Abstract

Objectives The purpose of this article is to determine how many of the current peer-reviewed studies of ankle foot orthoses (AFOs) on children with cerebral palsy (CP) have included adequate details of the design and material of the AFO, to enable the study to be reproduced and outcomes clearly understood.

Methods A thorough search of studies published in English was conducted in March 2015, with no restriction on dates, within all major databases using relevant phrases. These searches were then supplemented by tracking all key references from the appropriate articles identified.

Study selection The inclusion criteria were as follows: (1) population - children with CP; (2) intervention - AFOs; and (3) outcome measure. One reviewer extracted data regarding the characteristics of the included studies, with the extracted data checked for accuracy and completeness by a second reviewer.

None of the studies reviewed gave adequate details of the AFOs. Only 3.6% (n = 2) of papers tested the stiffness. Many studies (54.5%) did not describe the material used nor the material thickness (72.7 %). None of them gave any clinical justification for the chosen design of AFO.

Conclusions There is a clear paucity of detail regarding the design and material used in AFOs on studies involving children with CP. Such a lack of detail has the potential to affect the validity of the reported outcomes, the ability to reproduce the studies and may misinform clinical practice.

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Cite this article: Eddison N, Mulholland M, Chockalingam N. Do research papers provide enough information on design and material used in ankle foot orthoses for children with cerebral palsy? A systematic review. *J Child Orthop* 2017;11. DOI 10.1302/1863-2548.11.160256

Keywords: orthotic devices; cerebral palsy; AFO, orthoses; materials testing; clinical outcomes

Introduction

Patients with cerebral palsy (CP) are the most commonly observed participants in gait laboratories.[1] CP is thought to be the most common cause of serious physical disability in childhood, although it only affects two to three per 1000 live births.[2] CP is primarily characterised by central nervous system abnormalities, such as loss of selective motor control and abnormal muscle tone. As a result of growth, these primary characteristics often lead to secondary deficits, including bony deformities, muscle contractures and gait abnormalities.[3] In addition to surgical and therapeutic interventions, orthoses play an important role in the management of the child with CP.

An orthosis is defined by the International Standards Organisation as 'an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system'.[4] Ankle foot orthoses (AFOs) are commonly prescribed to children with CP in an attempt to improve their gait; they are defined as 'orthoses that encompass the ankle joint and the whole or part of the foot'.[5] AFOs are intended to control motion, correct deformity and/or compensate for weakness.[6]

There are a wide variety of AFOs used in clinical practice, which are characterised by their design, the material used and the stiffness of that material. Changing any of these three components will alter the control the AFO has on the patient's gait.[7] The inherent rigidity of an AFO has been demonstrated to play an important role in determining its biomechanical function and needs to be optimal to positively influence pathological gait.[8,9] The rigidity of an AFO may be determined by a number of factors, such as the mechanical properties of the material, the trim lines, the material thickness and the shape of the

superstructure.[10-13] Lunsford[14] reported that the variation in the material properties used in the manufacturer of an AFO may influence the flexibility at the ankle and metatarsophalangeal joints (MTPJs) of these 'rigid' devices and it is documented in the current literature that differences in mechanical properties of the AFO occur as a consequence of relatively minor variations in AFO design.[15-18]

Limitations relating to AFO design and inappropriate prescription to facilitate for an individual's movement pattern can hinder the effectiveness of AFOs.[19] By the same reasoning, inappropriate design and prescription of AFOs can have substantial influence on research results.

If changing the design, material and stiffness alters the control the AFO has on the individual's gait, then it stands to reason that a detailed description of the AFO used in research studies is imperative, along with a justification of why the AFO was designed with each particular characteristic and what the aim of the design is. For example, if one uses a 3-mm natural polypropylene AFO with trim lines behind the MTPJs, with an ankle of the angle in the AFO (AAAFO) of 90°, on a person who weighs 14 stone (196 pounds) with fixed pronation of the foot and excessive knee flexion during stance phase and a plantar flexion contracture, one is likely to conclude that the AFO was an unsuccessful intervention in controlling this patient's gait when the actual conclusion should be the AFO design was inappropriate. The AFO would be inappropriate on the basis that 3-mm natural polypropylene would not be strong enough to control the gait deviations of a patient who weighed 14 stone/196 pounds, a lack of a lateral flange past the fifth met head would allow the foot to move off the footplate and offer no control to the forefoot abduction caused by pronation. The third rocker would not be blocked and the true length of gastrocnemius would not be accommodated in a 90° AFO, thus increasing knee flexion further and preventing knee extension at terminal stance.

There are wide ranging studies in the current literature which have studied a variety of outcomes with regards to the use of AFOs on children with CP, including spatiotemporal parameters, energy expenditure, joint kinetics and kinematics, sit-to-stand transfers and walking ability. A detailed description of the variation and efficacy of AFOs is beyond the scope of this article but is described widely within the published literature.[20-23] There is variability regarding the efficacy of AFOs on the gait of children with CP; this may partially be due to inappropriate AFO design to match the presentation of the patient. The evidence base for the use of AFOs in children with CP has been repeatedly described as low quality.[21-24]

Previous papers[22,25] have recommended reporting guidelines for AFO interventions to enable the quality of the AFO intervention to be more accurately assessed. Recommendations include: the movements prevented, assisted and permitted by the AFO; foot plate length and flexibility; trim-line position; materials; method of manufacture; and testing of mechanical stiffness of the AFO; concluding 'Transparent reporting permits replication of the study, and makes it possible to understand the variables that may affect intervention outcomes'.[25]

The aim of this paper is to perform a systematic review on the current literature pertaining to studies on AFOs in children with CP, with emphasis on the detail of the design and material of the AFO offered in each paper. A secondary aim is to analyse the outcome measures used in each study. The authors recognise that there are numerous other essential aspects of reporting regarding AFO research, e.g. the shank vertical angle, the footwear combination, the tuning process and the physical presentation of the child; these have been described in the current literature[25-29] and will not be detailed in this paper.

Methods

Data sources

This systematic review of databases was performed in March 2015. The following 14 databases were searched: Web of Science, Medline, PubMed, CINAHL Plus, EMBASE, SCOPUS, Rehabdata, PsycInfo, ERIC, Education Research Complete, Business Source Complete, IEEE, NIHR and CEA Registry The search used the following key words: 'AFO', 'ankle foot orthoses', 'cerebral palsy' and 'CP'. No language restriction was applied to the search. Searches were adapted for each database and were completed between 10 and 20 March 2015.

Study selection

Inclusion/exclusion criteria

Two reviewers independently screened the search results.

Inclusion criteria:

- Papers which studied AFO/s on children (aged 18 years and under) with a primary diagnosis of CP.
- Studies which measured an outcome, excluding patient perception studies.
- Studies which were in English.
- Full studies which were located in a peer-reviewed journal.

Exclusion criteria:

- Expert opinion articles; letters to the editor; commentaries, abstracts and systematic reviews.
- Studies involving participants aged over 18 years.
- Studies which involved participants who did not have a diagnosis of CP.

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Data extraction and methodological quality appraisal

One reviewer extracted data regarding the characteristics of the included studies, with the extracted data checked for accuracy and completeness by a second reviewer. For the extracted data checklist see Table 1.

Results

The electronic database search identified 947 articles pertaining to the study of AFOs. Following the application of the inclusion criteria, 55 papers met the criteria imposed by this review. Appendix 1 outlines the extracted data from various included studies. See Table 2 for grouped data per question.

The main results of this review show that the most commonly tested AFO is a bespoke (58.2%), hinged AFO (21%). The AFO material most commonly used of those who stated material used (43.6%) was polypropylene (83.3%) in 3-mm thickness (n = 7). The outcome most commonly measured was lower limb kinetics, kinematics and temporal spatial parameters during gait (n = 25).

Only 3.6% of the papers reviewed carried out stiffness testing on the AFO intervention they used; 61.8% of papers failed to give any description of the footplate, the trim lines at the ankle (69%), the height of the AFO (67.3%), the material thickness (72.7%) and the ankle of the angle in the AFO (AAAFO) (54.5%).

Table 1. Extraction data.

AFO design	Choose response
Is the type of AFO described?	Type of AFO/Incomplete/-
Is the AFO bespoke or stock?	Bespoke/Stock/-
Is the AAAFO described?	Yes/-
Is the manufacturer of the AFO identified?	Complete/-
Are the trim lines of the ankle described?	Complete/Incomplete/-
Are the trim lines of the foot plate described?	Complete/Incomplete/-
Is the height of the AFO described?	Complete/Incomplete/-
Is the strapping system described?	Complete/Incomplete/-
Is there detail of the stiffness of the AFO in stance phase?	Complete/Incomplete/-
If hinges are stipulated are these described?	Complete/Incomplete/-
Is there a justification for choosing the AFO design?	Complete/Incomplete/-
AFO material	
Is the material described?	Material/-
Is the thickness of the material described?	Thickness/-
Is there a justification for choosing the material and thickness?	Complete/incomplete/-
Has stiffness testing been carried out?	Yes/-

Complete, all information present; Incomplete, some information missing; N/A, not applicable to this paper; -, all information missing

Discussion

The research included within this study examined the effect of AFO use on a range of outcome measures in children with CP. As stated in previous reviews,[21,22,25,30] there was considerable variety in both the level and quality of the details reported. The results show that none of the papers reviewed adequately described the design and material of the AFO being studied. In all of the papers reviewed, AFOs were the main intervention from which the outcome was measured. Thus, it is inconceivable that such a lack of detail on the main intervention should be provided. In many cases this lack of detail limits any assessment of intervention quality and the impact that this may have on the confidence of findings. This variability also means that it is not possible to analyse or pool the data in a structured way to conduct some sort of meta-analyses which can summarise results across studies to provide substantial evidence for treatment practices.

The paucity of detail regarding AFO design and justification in the current literature may be responsible for producing variation in reported outcome measures, e.g. temporal-spatial parameters,[31,32] ankle kinematics[32-34,35] and knee kinematics.[36] Van Gestal et al reported 'when reading (recent) literature, the researcher is often confronted with contradictions in reported effects of certain AFOs on gait';[37] however, this paper failed to report full details of the material used in all AFOs studied, the footplate design and flexibility, the material thickness, ankle trim lines and the AAAFO. Similarly, Davand et al reported 'The importance of the choice of appropriate AFOs in improvements of standing and walking in these children are quite critical. When an orthotic is given correctly, the participant will perform activities of daily living (ADLs) better and more independently.'[38] However, Dalvand et al failed to include the full details of the AFOs issued to their participants, including trim lines at the ankle, type of hinged used, strapping system, footplate design, stiffness of the material used and the justification of the chosen AFO design.[38]

Furthermore, there is a lack of standardisation for the terminology used to describe each type of AFO. Thus, there is no clear definition on what constitutes a 'solid' AFO. The term is often used to describe an AFO with trim lines anterior to the malleolus but made from a material which allows deformation at the ankle joint during gait. Others will use the term 'solid' to denote a rigid AFO with anterior trim lines and no movement at the ankle during stance phase.

Thus, stating that an AFO is 'solid' in design is not enough to determine its potential effects on gait or ensure that a study is reproducible and its outcomes correctly evaluated. Although the literature reports several different types of AFOs, it is often not clear which type of AFO is

Table 2. Data extraction grouped per question.

	Data Extracted:
Is the type of AFO described?	See Fig. 1
Is the AFO bespoke or stock/off the shelf?	32 papers reportedly used bespoke AFOs 1 paper reportedly used bespoke and stock 1 paper used stock 21 papers did not state
Is the AAAFO described?	15 papers described the AAAFO 10 papers gave incomplete details 30 Papers did not state
Is the manufacturer of the AFOs described?	6 papers detailed the manufacturer 1 paper gave incomplete details 48 papers did not state
Are the trim lines of the ankle described?	10 Papers detailed the trim lines at the ankle 7 papers gave incomplete details 38 papers did not state
Is the full design of the footplate described, including length, stiffness and medio-lateral borders?	0 papers gave a full description of the footplate 21 papers gave an incomplete description of the footplate 34 papers did not state any description of the footplate
Is the height of the AFO described?	14 papers described the height of the AFO 4 papers gave an incomplete description 37 papers did not describe the height of the AFO
Is the strapping system described?	9 papers described the strapping system 5 papers gave an incomplete description 31 papers did not describe the strapping system
Is the stiffness of the AFO in the stance phase described?	9 papers described the stiffness of the AFO in stance phase 6 papers gave an incomplete description 40 papers did not state
If hinges are stipulated, are these described?	9 papers described the hinges on the AFO 2 papers gave an incomplete description 21 papers did not state 23 papers were N/A
Is the material described?	24 papers described the material used 31 papers did not state the material used 20 papers used polypropylene 2 papers used copolymer 1 paper used homopolymer 1 paper used graphite 1 papers used carbon fibre 1 paper gave an incomplete description
Is the thickness of the material described?	40 papers did not state the material thickness 1 paper stated 6 mm 1 paper stated 5 mm 4 papers stated 4.8 mm 1 paper stated 4.5 mm 4 papers stated 4 mm 1 paper stated 3.2 mm 7 papers stated 3 mm 1 paper stated 2.4 mm
Is there a justification for choosing the material and thickness?	2 papers gave a justification for material and or thickness choice 1 paper gave an incomplete description 52 papers did not state
Has stiffness testing been carried out?	2 paper carried out stiffness testing 53 did not state
What was the outcome measure of the study?	25 papers measured lower limb kinetics and kinematics of gait and temporal spatial parameters 10 papers measured energy expenditure 5 papers measured standing balance 4 papers measured functional motor skills 2 papers measured sit to stand transfers 2 papers measured stair locomotion 2 papers measured trunk posture 2 papers measured EMG 3 papers measured knee extension 1 paper measured level walking 1 paper measured ankle function 1 paper measured skin tissue pressure mobility 1 paper measured ankle range of motion 1 paper measured hamstring length 1 paper measured functional balance 1 paper measured ambulation 1 paper measured static foot alignment 1 paper measured lower limb intersegmental co-ordination 2 paper measured gross motor function 1 paper measured pelvis, thorax and arm kinematics

being used for the intervention. For example, five of the papers reviewed termed their AFO as 'rigid', six used the term 'fixed' and 19 used 'solid'(Fig. 1). Due to the aforementioned lack of standardisation of terminology, it is unclear whether these papers are all using the same style of AFO. Hinged AFOs (n = 20) were the most common intervention in the studies reviewed. It is critical to ensure that the length of gastrocnemius can be accommodated in a hinged AFO; a failure to do so will result in compensations at the knee and hip.[26-29] Without sufficient details regarding the prescription and clinical reasoning for the provision of a hinged AFO, it is difficult to summarise its effectiveness.

Dursan et al,[39] Olama et al,[40] Kott and Held[41] and Mossberg et al[42] do not state which type of AFO has been used and offer no other details of the AFO design. This means that the results published are of little value. Partially, as the validity of the papers and repeatability are poor and therefore the results have limited clinical value, one is unable to draw conclusions from the results.

The 32 papers used bespoke AFOs and one paper used both stock/off-the-shelf and bespoke AFOs; however, 21 (38.2%) papers have not stated whether the AFOs were stock or bespoke. For this reason, it is difficult to surmise whether the AFO used fits the participant appropriately and whether fit issues could have had an effect on the results. Only six papers stated the manufacturer used for the AFO; thus, there is a possibility that the experience of the technician may have had an impact on AFO effectiveness.

Differences in the mechanical properties of the AFO can arise from small variations in AFO design such as trim-line position and choice of materials.[25] A method of measuring the stiffness and neutral angle around the ankle and MTPJs has been demonstrated as clinically applicable.[16,43] However, only two (3.6%) papers demonstrated the stiffness of the AFO during stance phase, which means that the control given by the AFO is only known within these two papers. Thus, whether the AFO had adequate control is unknown, potentially affecting the results of these studies.

The 31 (56.4%) papers did not state the material used in the AFO. Of the 24 papers which did state the material, the majority (83.3%) used polypropylene. However, when stating polypropylene, researchers did not given details on the type of polypropylene used, e.g. natural or homo polypropylene, both of which have different characteristics. Furthermore, 72.7% of researchers did not state material thickness. The current literature has indicated that both the material used and thickness have an effect on the rigidity and flexibility of the AFO; the fact that researchers are not stating this means the reader is unable to tell if the results of the study are from the AFO being an inappropriate material or thickness, or whether AFO intervention was unsuccessful. Of those papers who did state material thickness, the most common thickness used was 3 mm (n = 7). Only two papers justified the reasons for giving the AFO material and thickness.[44,45]

The 21 papers (38.2%) gave a partial description of the footplate design and 34 papers (61.8%) failed to give any description of the footplate design. None of the papers included within this review offered a full description of the footplate design. The height of the AFO was described by 14 papers (25.5%) with only ten papers (18.2%) fully describing the trim lines of the AFO at the ankle and six papers (10.9%) detailing a partial description of trim lines at the ankle. As trim lines have such a significant impact of the rigidity and function of an AFO, omitting the details of the trim lines of an AFO, means it is difficult to know the function of the AFO and how appropriate the design of the AFO was in trying to produce the desired outcome.

There was a failure in all studies reviewed to give a clinical justification for the AFO design used. Thus, the chosen AFO prescription and desired function is unclear. Gage[46] reports the selection of the proper orthotic design should be based on an understanding of the primary gait deviations of the patient. Therefore, it is difficult to assess how the AFO design impacted the results, or whether the design was inappropriately chosen for the participant, and whether this had a detrimental effect on the results.

Only 15 (27.3%) papers detailed the AAAFO, the choice of which depends on clinical measures such as the passive and dynamic gastrocnemius muscle length and tri-planar foot stability. If there is severe spasticity or contracture in this muscle it must be accommodated within the AAAFO to avoid limiting maximum knee extension or compromising the tri-planar stability of the foot.[47] If the passive gastrocnemius length is also reported in addition to the AAAFO, the reader can confirm that prescription is appropriate. Furthermore, if a paper is reporting on a hinged AFO which allows free dorsiflexion (one could refer free dorsiflexion to a hinge with no dorsiflexion stop) and such a device is being used on a participant with a plantar flexion contracture, the reader will be able to deduce that such a device will detrimentally effect knee extension and/or foot position.

The CP consensus conference (the aim of which was to determine the evidence to support the efficacy of lower limb orthoses used for children with CP) in 1994 concluded that: 'The existing body of literature on the effects of orthotic intervention in cerebral palsy is, for the most part, seriously scientifically and experimentally flawed'.[24] Unfortunately, in terms of description of device used, the situation appears to have changed very little in the last 20 years.

A full analysis of the papers included in this systematic review is available in the appendix.[48-85]

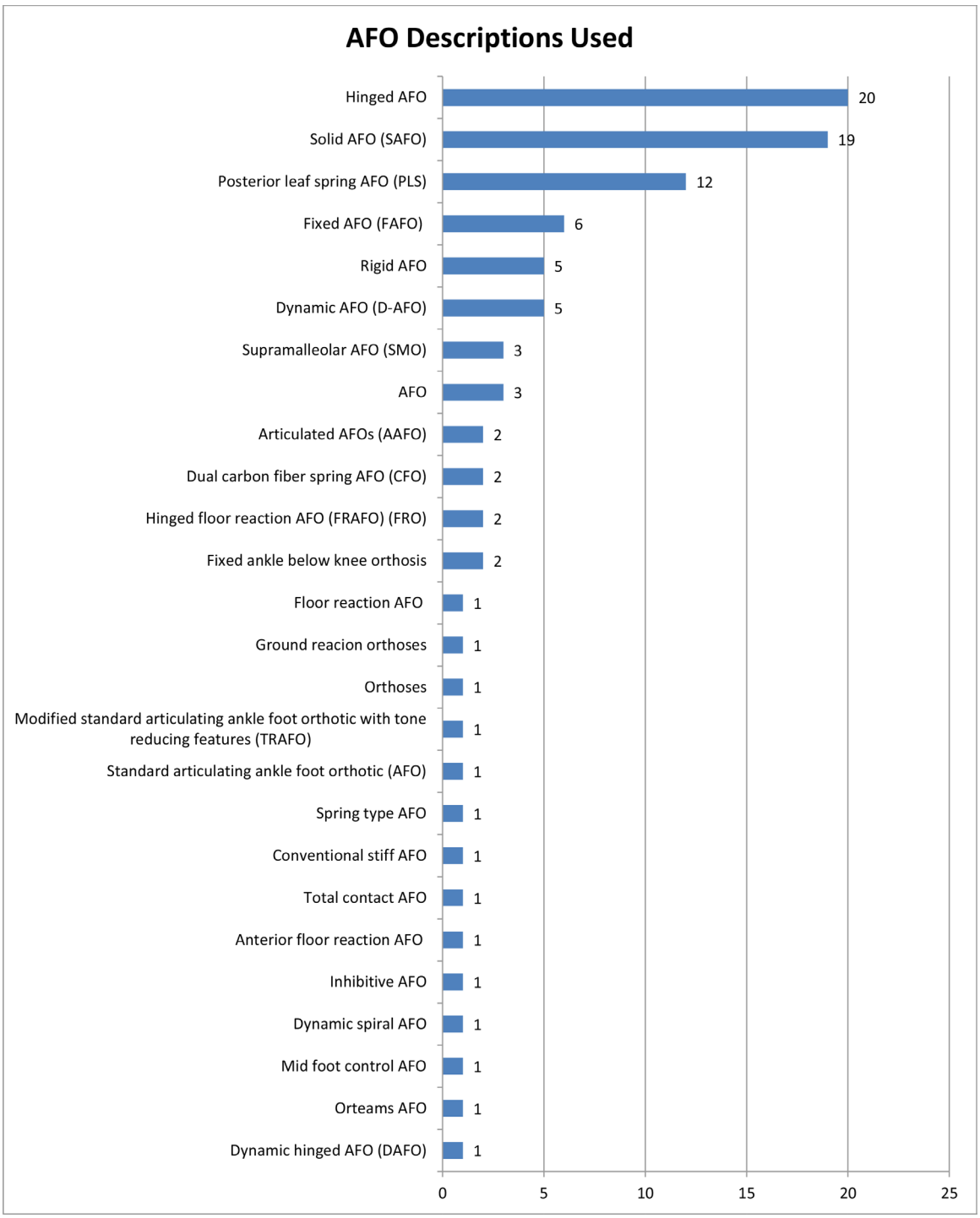

Fig. 1 The type of ankle foot orthoses (AFO) design reported in each study.

Based on the systematic appraisal of the current literature, future studies should include the following recommendations:

- The material of the AFO used as an intervention in a research study should be detailed, including type, thickness and any reinforcements.
- The full design of the AFO should be described, including trim lines at the ankle, footplate design, length, medial and lateral flanges and flexibility, strapping arrangement and reinforcements.
- The stiffness of the AFO in stance phase should be described.

- The type of AFO used should be described and a justification of the choice of design should be detailed.
- The AAAFO should be detailed along with a justification of the chosen AAAFO.

Transparent reporting permits replication of the study and makes it possible to understand the variables that may affect intervention outcomes.[25] It is therefore recommended that journals reviewing future research on AFOs should reject papers which do not include the full details of the AFO intervention as outlined above

Limitations

One of the perceived limitations of this study could be that it did not assign quality scores or rank studies, or look at the sample sizes or method outside of the materials and AFO design. With this in mind, one could argue that the scope of this study is limited, However, the reported results clearly indicate that there is a substantial lack of structured information within the published research papers which needs to be addressed.

Future research

Further research is needed on AFO prescription protocols. The AFO prescription process is largely empirical, resulting in confusing results regarding treatment efficacy. Development of prescription protocols will help ensure the design of AFOs in future research can be better compared and outcome measures validated, thus leading to improved clinical practice, based on evidence-based AFO provision. An agreed consensus on outcome measures will allow researchers to cross-reference research and enable validated meta-analyses to be performed. Terminology used to describe AFOs needs to be standardised to ensure studies can be reproduced and readily compared and evaluated.

Appendix

An appendix showing the data extracted from all papers is available online with this paper.

Received 6 December 2016; accepted after revision 5 April 2017.

COMPLIANCE WITH ETHICAL STANDARDS

FUNDING STATEMENT

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

ETHICAL STATEMENT

No funding was received for this study.

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