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N Eddison, A Healy, D Buchanan, N Chockalingam

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Standardised classification system for bespoke thermoplastic ankle foot orthoses

Eddison N, Healy A, Buchanan D and Chockalingam N

Centre for Biomechanics and Rehabilitation Technologies, Staffordshire University, Stoke, United Kingdom.

Nicola Eddison PhD[1,2]
Consultant Orthotist/Associate Professor of Orthotics
Twitter: @OrthoticNetwork

Aoife Healy PhD[1]
Associate Professor of Human Movement Biomechanics
Twitter: @ AoifeCHealy

Dave Buchanan[3]
Technical Director
@Daveblanche

Nachiappan Chockalingam PhD[1]
Professor of Clinical Biomechanics
Twitter: @ NachiC

[1]Centre for Biomechanics and Rehabilitation Technologies,
School of Life Sciences and Education,
Staffordshire University,
Leek Road,
Stoke-on-Trent,
ST4 2DF,
United Kingdom

[2]The Royal Wolverhampton NHS Trust,
New Cross Hospital,
Wednesfield Road,
Wolverhampton,
WV10 0QP,
United Kingdom

[3] TalarMade Orthotics Limited
Edinburgh House
Millenium Way
Chesterfield
S41 8ND
United Kingdom

Address for Correspondence:

Nicola Eddison PhD
Centre for Biomechanics and Rehabilitation Technologies
Staffordshire University
Leek Road

Stoke on Trent ST4 2DF
Phone: + 44 1782 295853
Email: Nicola.Eddison@staffs.ac.uk

Abstract

Purpose: To validate a new classification system for bespoke thermoplastic ankle foot orthoses (AFOs).

Methods: Inter- and intra-observer reliability study. A classification system based on the design and function of AFOs was created. Sixty-three independent observers classified thirty-six photographs of different AFOs, according to the proposed classification system via an online questionnaire. Approximately two weeks later, the same AFOs were classified again by fifty-three of the same participants. All participants were health care professionals, researchers, or technicians with experience in referring for, prescribing, fitting, reviewing, researching or manufacturing AFOs.

Results: The mean inter- and intra-observer agreement Fleiss' kappa was 0.932 and 0.944, respectively. 98.3% of participants reported that the classification system was very easy or moderately easy to use, with 85.7% reporting they would use the classification system. 90.5% of participants reported that the proposed AFO classification system was clear, with 84% stating it was useful.

Conclusion: The proposed classification system for bespoke thermoplastic AFOs, has an excellent inter- and intra-observer agreement. It will reduce the ambiguity of the description of the type of AFOs used in clinical practice and research. Furthermore, it makes reproducible comparisons between groups possible, which are essential for future evaluations of evidence-based orthotic care.

Keywords: ankle foot orthoses, orthotics, terminology, classification systems, evidence based medicine.

Introduction

The first known reference to an ankle foot orthosis (AFO) dates back to 1791(1), describing a device that looks very similar to the designs we see today, encompassing the foot and ankle and terminating below the fibular head. Unlike today's devices, it was made from tin. Descriptions of polypropylene AFOs started to appear in the literature in the early 1970s(2,3) and is the primary material used in the manufacturer of the majority of bespoke AFOs today. The term ankle foot orthosis (AFO) has been standardised by the International Organization for Standardization (ISO)(4–6) and defined by the British Standards Institute(7). ISO 13404(8) offers categorisation and description of external orthoses and orthotic components. However, it is important to point out that these definitions and standardisations only apply to the term "AFO" and its components, there is no classification for the different *types* of AFOs.

There are a wide variety of AFOs used in clinical practice, which are characterised by their design. The current literature also indicates that differences in mechanical properties of an AFO occur as a consequence of relatively minor variations in design(9–12).

The ambiguity of acronyms

An AFO which blocks movement in all three planes is often termed a solid AFO (SAFO), a fixed AFO or a rigid AFO (see figure 1). However, the term solid AFO can be used to describe an AFO which has trimlines anterior to the malleoli but allows deformation of the material during stance phase; others will use the term to describe an AFO which has no deformation during stance phase. To confuse matters further, the acronym SAFO is also used to describe a very soft silicone AFO. Rigid is an expression of stiffness, and as such should be considered a more appropriate description than "solid". The rigidity of an AFO may be determined by a number of factors, such as the mechanical properties of the material, the

trimlines, the material thickness and the shape of the superstructure(13–16). The inherent rigidity of an AFO has been demonstrated to play an essential role in determining its biomechanical function(13,17,18).

**Insert figure 1 near here

AFOs which incorporate an articulation allowing a degree of dorsi-flexion are termed hinged AFOs (HAFOs) or articulated AFOs (A-AFO), the term articulated AFOs seems more appropriate as not all articulations have hinges (See figure 2).

**Insert figure 2 near here

AFOs can be designed to incorporate the knee joint thus attempting to apply an extension moment at the knee; these are often termed ground reaction force AFOs (GRAFOS or GROs) but are also called floor reaction AFOs (FRAFO) and can be designed as a one-piece device or a two-piece device but have the same name (see figures 3 and 4). Saltiel(19) designed the original GRO in an attempt to provide people with polio with "a more physiological gait than that afforded by a rigid knee" as in a knee ankle foot orthosis (KAFO). The participants in Saltiel's study(19) all walked in equinus on their toes with no heel contact, very different to how GROs are used today. Regardless of the original design, there is no evidence that a rigid AFO with an anterior shell affects the ground reaction force any differently than an AFO without a shell therefore the terms GRO and GRAFO need revising.

**Insert figures 3 and 4 near here

AFOs terminating just above the malleoli are commonly termed supra-malleollar orthoses (SMO) and are believed to offer control in the coronal and transverse planes only. SMOs which incorporate a "neurological" or "inhibitive" footplate, terminating just above the malleoli are commonly termed dynamic AFOs (DAFO). The DAFO evolved from the use of inhibitive casting by therapists to control abnormal muscle tone in children with spastic cerebral palsy during the 1970s(20). The term "dynamic" is ambiguous with no clear meaning. Therefore, the use of the term "supra malleolar AFO" seems more appropriate along with any further description of modifications to the footplate (see figure 5).

**Insert figure 5 near here

AFOs with trimlines posterior to the malleolar are said to offer some energy return and can also be termed DAFOs, more commonly they are termed posterior leaf spring AFOs (PLS). Other terms used are flexible AFOs, tone reducing AFOs (TRAFO), spring Type AFOs and conventional AFOs (See figure 6), with the variation in material properties influencing their flexibility(21).

**Insert figure 6 near here

Another commonly used term is a "piggyback" AFO, which is ambiguous and gives no indication of the design of the AFO, and usually consists of one design of AFO sitting inside another.

A systematic review conducted by Figueiredo et al.(22), examining the efficacy of AFOs on the gait of children with cerebral palsy, reported that amongst the 20 studies reviewed there

were 12 different terms used to describe the AFOs studied, with differing terms used to describe the same AFOs. The paper reported that the variety of types and descriptors of the AFOs made it difficult to summarise results.

Clinicians and researchers alike are unequivocal that not all AFOs are the same, they don't treat the same pathologies and different designs have significantly different effects on biomechanical function. Yet the terms used to describe the different types of AFOs have not been classified and defined, with descriptions and acronyms differing between researchers and clinicians; resulting in poorly designed research studies(22,23), individual interpretation and a misunderstanding of research outcomes. The lack of classification has resulted in generalisation on the effects of AFOs from research studies which have not been clear on the design of the AFO used or the presenting pathology it was used for(23), with some studies describing the AFO as "a standard AFO"(23) for which there is no definition.

Standardised terminology and definitions for AFOs are critical in clinical practice, without these, there may be serious negative consequences, with the potential to cause harm(24,25). Researchers have raised similar issues with a lack of standardisation for other aspects of orthotic intervention(24). The primary objective of this study is to validate a new classification system for different designs of bespoke thermoplastic(26) AFOs, by measuring the inter- and intra-observer agreement.

Method

The approach utilised in this study follows the design used by Holla et al.(27) for the classification of cervical spine immobilisation. To determine the inter- and intra-observer agreement, photographs of different AFOs were classified via an online questionnaire using

Qualtrics (Qualtrics International, USA) , by observers from a range of health care professions involved in the provision of orthotic care. The group comprised of practising clinicians, researchers and orthotic technicians working in different healthcare settings and systems around the world *(see table 1).* The 1st questionnaire, to assess interobserver agreement, consisted of 51 questions in total with 36 classification questions (see appendix 1 for the full questionnaire). The remaining 15 questions asked for:

- the participant's profession
- if they were aware of any classification system which provides names for the different types of bespoke thermoplastic AFOs
- if they thought there was a need for a classification system
- if they thought the presented AFO classification system was clear
- the usefulness of the presented AFO classification system (ease of use, effectiveness, and likelihood of using the proposed classification in the future)

To assess intraobserver agreement a 2nd questionnaire, consisting only of the 36 classification questions, was distributed to the same participants approximately two weeks after completion of the 1st questionnaire.

The research project was approved by the Staffordshire University Research Ethics Committee (Ref. SU20-161-RN). Informed written consent was sought and recorded from all participants. The survey opened on 15th July 2021.

The classification system consisted of six categories of AFOs, using the same terminology as ISO 13404(8):

- ***Rigid AFO*** - (using the term "rigid" instead of "solid" as rigid is an expression of stiffness).
- ***Flexible AFO*** - (using the term flexible instead of the plethora of other alternative terms as it aligns with the term used in ISO 13404(8)).
- ***Articulated AFO*** - (using the term "articulated" instead of "hinged" as it aligns with the term used in ISO 13404(8)).
- ***Rigid AFO with separate anterior shell*** (Using the term "anterior shell" instead of "Ground reaction force AFO" as it aligns with the terms "anterior" and "shell" in ISO 13404(8) and because there is no evidence that AFOs with anterior shells affect the ground reaction force any differently than an AFO without an anterior shell. Note distinction between incorporated and separate shell).
- ***Rigid AFO with incorporated anterior shell*** - (Using the term "anterior shell" instead of "Ground reaction force AFO" as it aligns with the terms "anterior" and "shell" in ISO 13404(8) and because there is no evidence that AFOs with anterior shells affect the ground reaction force any differently than an AFO without an anterior shell. Note distinction between incorporated and separate shell)
- ***Supra-malleollar AFO*** - (Using the term "Supra-malleollar" instead of "dynamic" due to the ambiguity of what is dynamic about the AFO and the fact that dynamic is used to describe several different types of AFOs with no clear definition.

This proposed classification system is only related to terminology, it is not a guide for AFO specification/prescription. It is intended to ensure that there is a standardisation of terminology when describing the design of an AFO.

• *Classification system:* The new classification system, as described above and shown in

Figure 7, was presented to all participants before they were asked to classify the AFO photographs, and at the start of each subsequent block of nine photographs, participants were also issued with a separate pdf of the classification system to refer to at any time.

**Insert figure 7 near here

• *Selection of observers:* The authors approached potential participants through their professional networks and incorporated snowball sampling by asking participants to identify other potential participants. A total of 63 participants took part in this study as observers (table 1). To increase the clinical validity, we sought to recruit participants from different occupations and countries, working across different healthcare systems.

**Insert table 1 near here

- *Selection of photographs and devices:* 36 photographs of different AFO designs were selected from the authors' own database. The photographs had to meet the following criteria: anterior and/or lateral view of the AFO, full colour, all photos were given a blank background.
- *Assessment process:* All the participants (n=63) classified the 36 photographs independently without time limitation via an online questionnaire. All photographs were randomised (round one of the survey).

Before and after the classification all participants answered several questions about the clinical usefulness of the classification.

After at least 13 days (mean: 26.4 days, range: 13–44 days), the same photographs in a different random order were again classified by the same participants (n=53) (round two of the survey). The observers did not have access to their earlier answers after they completed the forms.

- *Analysis:* For determination of the inter- and intra-observer agreement, Fleiss' kappa was calculated based on a nominal scale with a qualitative variable using IBM® SPSS® (Statistics for Windows, Version 27.0). The kappa score was interpreted as described by Landis and Koch (28).

Results

There was a technical error on the online questionnaire for photograph 6.6 which prevented it from being available to all participants, therefore, this photograph was removed from the analysis, leaving a total of 35 photographs to be analysed.

Interobserver agreement n= 63 participants

Fleiss' kappa was run to determine if there was an agreement between participants' judgement on the 35 photographs of AFOs using the proposed classification system. There was excellent agreement between the participants classification of the AFOs $\kappa = .932$ (95% CI, .929 to .936), $p < .0005$. Individual kappa for the six types of AFOs were .913 for Rigid, .919 for Flexible, .956 for Articulated, .946 for Rigid with separate anterior shell, .886 for Rigid with incorporated anterior shell, and .978 for Supra-Malleollar.

Intraobserver agreement: n= 53 (10 participants out of the original 63 failed to respond to round two of the survey). Fleiss' kappa was run to determine the intraobserver agreement,

comparing the participants responses in round one to their responses in round two. There was excellent agreement with a mean $\kappa = .944$ (range 0.404–1, standard deviation: 0.11), $p < .0005$. Furthermore, 29 participants had an individual Kappa score of $\kappa = 1$ and five participants had a Kappa score of < 0.8.

Clinical usefulness:

**Insert table 2 near here

Discussion

The results of this study show that 74.6% (n= 47) of participants agreed that there is a need for a classification system for AFOs, of those who responded "no" (n=3) or "unsure" (n= 13) none gave an explanation as to why they thought there was no requirement for an AFO classification system. 76.1% (n=48) of participants stated that they did not know of any AFO classification system, of the 23.8% (n=15) who stated they did know of a classification system for AFOs, the systems they named did not classify AFOs (n=5), was an unknown/unpublished classification system (n=1) or gave no response (n=9). There are no validated classification systems for the different types of bespoke thermoplastic AFOs in the current literature.

90.5% (n=57) of participants reported that the proposed AFO classification system was clear, with 84% (n=53) stating it was useful, of those who stated it was not useful (n=2) or they were unsure if it was useful (n=8), none gave a response as to why they thought it wasn't useful. 87.3% (n=55) also reported having no issues using the classification system, of the eight participants who reported having issues with the classification system, unclear photographs were the main cause (n=4), along with an apparent misunderstanding of the

purpose of the classification system, with responses noting that it does not contain all possible permutations of AFO design. However, the purpose of the classification system is to provide a category for the different types of bespoke thermoplastic AFOs not the many intricate differences in design.

66.6% (n=42) reported the classification system to be very easy to use with a further 31.7% (n=20) stating it was moderately easy. 85.7% (n=54) reported they would use the classification system.

According to Landis and Koch, the inter- and intra-observer agreement kappa values of this classification are rated “almost perfect”(28).

The classification system should be used as a basis for all bespoke thermoplastic AFO designs to negate the ambiguity of the current non-standardised terms used to describe AFOs. This classification is the basis to providing research which can be properly interpreted and for meta-analyses to be performed, this does not negate the need for researchers to provide full details of the individual design of the AFO including, foot plate length, medial-lateral borders of the foot plate, strapping system, material type, joint type and thickness (23,29,30).

The classification system is not intended to be used as a prescription guide, the function of the AFO and characteristics of the materials and the outcomes on differing pathologies is beyond the scope of this work. For example, a rigid AFO will produce a variety of outcomes depending on the design of the footplate, the addition of stiffeners, the thickness and type of polypropylene chosen and the strapping system, along with the presenting pathology it has been prescribed for. However, it will still be a “rigid AFO” and this standardardisation of

terminology allows the reader to understand which type of AFO is being tested and in turn allows necessary meta-analyses.

Currently there are six categories included in the proposed classification system, future work could see additional categories added.

Strengths of this study

The introduction of a validated simple and clear classification system for bespoke thermoplastic AFOs, considered useful by 84% of observers. The study has excellent inter- and intra-observer agreement results and high validity due to 63 observers, from different occupations across 13 countries around the world.

No classification system for bespoke thermoplastic AFOs currently exists. This new validated classification is clinically relevant to improve communication between healthcare professionals, allow meta-analyses of AFO research and ultimately improve the treatment offered to AFO users. If adopted, it will be possible to group external treatment modalities using bespoke thermoplastic AFOs and to compare their effectiveness and clinical outcomes and perform meta-analyses. This classification is essential for better evidence-based treatment of pathologies requiring a bespoke thermoplastic AFO intervention.

Limitations:

This study relied on still photographic images of AFOs, four of the participants reported that the images were not always clear enough to determine the classification. Although this is a limitation of the current study, it is not a limitation of the classification system as it is

envisaged that the system would be used by researchers, clinicians and technicians using the physical AFO they are manufacturing, studying, or issuing to a user.

Brief summary

- Standardised terminology and definitions for AFOs are critical in clinical practice, without these, there may be serious negative consequences, with the potential to cause harm.
- No classification system for bespoke thermoplastic AFOs currently exists. This new validated classification is clinically relevant to improve communication between healthcare professionals.
- The proposed classification system for bespoke thermoplastic AFOs, based on AFO design and function has an excellent inter- and intra-observer agreement with Fleiss' kappa values of 0.932 and 0.944, respectively.
- 90.5% of the participants considered the classification to be clear.
- 85.7% of participants reported they would use the classification system.
- With this validated classification system, it will be possible to compare different treatment options using bespoke thermoplastic AFOs and perform meta-analyses, which is essential for future evidence-based practice and research.

Disclosure statement:

All authors were fully involved in the study and preparation of the manuscript and declare that there is no conflict of interest.

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Tables:

Health care profession	Number of observers

Orthotists	47
Physiotherapists	7
Orthotic technicians	6
Researchers	3
Total number of observers	**63**
Country	**Number of observers**
Australia	14
Cambodia	2
Germany	1
India	7
Ireland	2
Italy	3
Malta	1
Philippines	6
Serbia	1
Singapore	5
Sri Lanka	2
Thailand	8
United Kingdom	11

Table 1: Professional background and country of the participants

Question	Answer		
Before classifying the devices			
Do you know of a classification system which provides names for the different types of bespoke thermoplastic AFOs?	Yes (n= 15)	No (n= 48)	
What is the name of the classification system? **If the participant answered yes to the previous question.*	Participant provided names of classification systems which do not classify AFO types (n= 5). Unknown classification (n=1) No response (n=9)		
Do you think there is a need for a classification system for the different types of bespoke thermoplastic AFOs?	Yes (n=47)	No (n= 3)	Unsure (n=13)

Why do you think/are unsure if there is a need for a classification system for bespoke thermoplastic AFOs? **If the participant answered no or unsure to the previous question.*	No response (n=16)			
Do you think the concept of the AFO classification system presented, is clear?	Yes (n=57)		No (n=6)	
After classifying the devices				
Having used the classification chart, do you think it will be useful in standardising the terminology used to describe bespoke thermoplastic AFOs?	Yes (n=53)	No (n=2)	Unsure (n=8)	
Why do you not think/are you unsure that the classification system is useful in standardising the terminology used to describe bespoke thermoplastic AFOs? **If the participant answered no or unsure to the previous question.*	No response (n=9)			
Having used the classification chart, how would you describe its ease of use?	Very easy (n=42)	Moderately easy (n=20)	Difficult (n=0)	Very difficult (n=1)
Did you have any difficulties identifying the AFOs based on the information provided in the classification system?	Yes (n=8)	No (n=55)		
What difficulties did you have identifying the AFOs based on the information provided in the classification system? **If the participant answered yes to the previous question.*	Photos unclear (n=4) Queries relating to additional footplate design and additional specification (n=4)			
Would you suggest any modifications to the classification?	Yes (n=27)	No (n=36)		
What modifications would you suggest? **If the participant suggested modifications in the previous question.*	Open ended questions n=26 Responses focused on introducing more categories to the existing six which would detail all types of trimlines, and movement permitted.			
Would you use the proposed classification system again?	Yes (n=54)	No (n=8)		
Why wouldn't you use the proposed AFO classification system? **If the participant answered no to the previous question.*	Using local guide (n=1) The classification isn't clear (n=2) Should include all design permutations (n=3) It would encourage clinicians to request an AFO based on the classification system rather than an individual specification (n=1).			

Table 2: Questions related to the use of the AFO classification system

Figure 1: An example of a rigid AFO

Figure 2: An example of an articulated AFO

Figure 3: An example of a rigid AFO with an incorporated anterior shell

Figure 4: An example of a rigid AFO with a separate anterior shell

Figure 5: An example of a supra malleolar AFO

Figure 6: An example of a flexible AFO

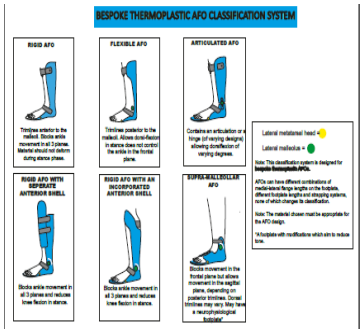

Figure 7: A bespoke thermoplastic AFO classification system

Highlights

- Standardised terminology and definitions for AFOs are critical in clinical practice, without these, there may be serious negative consequences, with the potential to cause harm.
- No classification system for bespoke thermoplastic AFOs currently exists. This new validated classification is clinically relevant to improve communication between healthcare professionals.
- The proposed classification system for bespoke thermoplastic AFOs, based on AFO design and function has an excellent inter- and intra-observer agreement with Fleiss' kappa values.
- With this validated classification system, it will be possible to compare different treatment options using bespoke thermoplastic AFOs and perform meta-analyses, which is essential for future evidence-based practice and research.
- With this validated classification system it will be possible to group external treatment modalities using bespoke thermoplastic AFOs and to compare their effectiveness and clinical outcomes. This classification is essential for better evidence-based treatment of pathologies requiring a bespoke thermoplastic AFO intervention