



Review

The impact of ankle-foot orthosis stiffness on gait: A systematic literature review

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ABSTRACT

Background: Ankle-foot orthoses (AFOs) are commonly prescribed to provide ankle support during walking. Current prescription standards provide general guidelines for choosing between AFO types, but are limited in terms of guiding specific design parameter choices. These design parameters affect the ankle stiffness of the AFO.

Research question: The aim of this review was to investigate the impact of AFO stiffness on walking mechanics.

Methods: A literature search was conducted using three databases: Pubmed, Engineering Village, and Web of Science.

Results: After applying the exclusion criteria, 25 of 287 potential articles were included. The included papers tested a range of stiffnesses (0.02–8.17 Nm/deg), a variety of populations (e.g. healthy, post-stroke, cerebral palsy) and various gait outcome measures. Ankle kinematics were the most frequently reported measures and the most consistently affected by stiffness variations. Greater stiffnesses generally resulted in reduced peak ankle plantarflexion, dorsiflexion, and total range of motion, as well as increased dorsiflexion at initial contact. At the knee, a few studies reported increased flexion at initial contact, and decreased peak extension and increased peak flexion during stance when stiffness was increased. Stiffness did not affect hip kinetics and there was low evidence for its effects on hip or pelvis kinematics, ankle and knee kinetics, muscle activity, metabolic cost, ground reaction forces and spatiotemporal parameters. There were no generalizable trends for the impact of stiffness on user preference.

Significance: AFO stiffness is a key factor influencing ankle movement. Clear reporting standards for AFO design parameters, as well as additional high quality research is needed with larger sample sizes and different clinical populations to ascertain the true effect of stiffness on gait.

1. Introduction

Ankle-foot orthoses (AFOs) are braces used to provide support about the ankle joint. Gait abnormalities commonly treated with AFOs include plantarflexor [1] or dorsiflexor [2] weakness, motor control deficits [3], spasticity [4], instability, and/or balance problems [5]. Three main categories of passive AFOs are available to address these deficits: non-articulated (also called solid-ankle or rigid); hinged or articulated; and posterior leaf spring (PLS) AFOs [6]. Recent guidelines for AFO prescription (e.g. [7–9]) provide recommendations for choosing between these categories. However, within each category of AFO, clinicians have to make numerous additional design decisions, e.g. drawing trimlines and material selection. These choices are likely to affect a patient's gait performance while wearing the device. Unfortunately, current clinical standards for choosing AFO design parameters are limited, likely because the impacts of design choice on patient outcomes are unclear.

One key AFO characteristic that can be affected by design decisions is the stiffness at the ankle. Here, AFO stiffness is defined as resistance

to sagittal plane rotation, described by the slope of the ankle torque vs ankle angle curve of an AFO. AFO stiffness is affected by trimline location and shape, as well as material type and thickness used for fabrication [10,11]. Clinical guidelines may suggest utilizing AFOs with higher rigidity for more severe patient deficits, for example, but do not provide specific, quantitative standards beyond this. Thus clinicians must rely on qualitative patient assessments and their own expertise to make these design choices.

An AFO's stiffness affects the level of support the AFO can provide, as well as its energy storage and return capacity, which would be expected to influence the gait performance of the user. More compliant devices may offer less support but greater energy return in comparison to their rigid counterparts. Rigid AFOs are often used to promote medial-lateral stability [12]. The increase in stability could manifest itself in increased preferred walking speeds [13] or lowered energetic cost [14]. In contrast, rigid AFOs can also help with spasticity. Muscle spasticity often results in stiff or tight muscles, which limit joint ranges of motion and cause hyper- or hypo-extension of the ankle or knee [4]. AFOs fabricated with a dorsiflexed neutral angle, for example, can

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prevent excessive plantarflexion of the ankle and bring its angle trajectory closer to normal gait. On the other hand, compliant PLS and hinged AFOs outfitted with spring-loaded or elastic joints can provide propulsion assistance. Depending on the location of the elastic components, energy is stored in the AFO during dorsiflexion or plantarflexion and released to aid individuals with plantarflexor [1] or dorsiflexor [2] weakness, respectively.

Several literature reviews have found positive effects of AFO-use in general on performance in various patient populations, including individuals with cerebral palsy [15], spinal-cord injury [16], multiple sclerosis [17] and those post-stroke [18,7]. However, none have explored the impact of AFO stiffness specifically, and many do not report it. In fact, a recent review by Eddison et al. [19] found that only 3.6% of research papers reporting AFO-use for children with cerebral palsy included AFO stiffness information. One recent review investigated the impact of a specific AFO, the Intrepid Dynamic Exoskeletal Orthosis (IDEO), on gait in individuals with lower-limb salvage [20]. The review included a brief discussion of the impact of AFO stiffness stating it significantly affected joint kinematics as a whole but had varying effect sizes. The specific parameters affected were not specified. The authors also found moderate-level evidence to support the claim that “stiffness should be considered with respect to patient preference.” Apart from the this article [20], which included only one type of AFO (the IDEO) and three stiffness values (described only qualitatively as “nominal, compliant and stiff”), there are no published systematic reviews investigating the effect of AFO stiffness on gait.

The purpose of this literature review was to determine whether AFO stiffness at the ankle has a significant impact on walking mechanics. The review focused on key outcome measures related to walking performance including lower limb kinematics and kinetics, muscle activity and metabolic cost of walking. Our secondary aim was to determine the specific stiffness ranges over which these parameters changed.

2. Methods

We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Guidelines as a methodological template for this review [21].

2.1. Search strategy

We conducted database searches in February 2018 using Pubmed (1781–2018), Engineering Village (Compendex & Inspec) (1666–2018), and Web of Science (1900–2018) with the following search terms:

- (ankle-foot orthosis OR AFO OR ankle foot orthosis) AND (stiffness OR resistance OR compliance OR rigidity OR flexibility OR energy storage OR energy return) AND (gait OR walking OR outcomes OR performance)

In the Pubmed database, the species was restricted to ‘human only’. Database search strategies are detailed in Supplementary Material A.

The search process is summarized in the flow diagram in Fig. 1. A single reviewer (DT) verified and removed duplicate works. Then, three reviewers (DT, MM, CJH) independently selected potentially relevant articles from titles and abstracts. Finally, the full text articles were screened against the following exclusion criteria:

- No experimental subject data was presented.
- The study did not include an AFO/AFO-like device.
- No comparisons were drawn across stiffness conditions or only one stiffness was tested for each subject.
- The intervention applied powered assistance and not passive resistance at the ankle.
- AFO stiffness varied (was not constant) within a single stiffness condition.

- The study did not test walking on level ground.

Each article was screened by two reviewers and final reasons for exclusion were agreed upon through consensus. When an article could be excluded using several criteria, a single reason for exclusion was chosen with priority given in the order listed. In addition to querying the databases, reference lists of included articles, and included and excluded review papers were reviewed for potential additional articles.

2.2. Assessment of study quality

The quality of each of the included articles was rated by three authors, using a modified PEDro scale [22] consisting of a 10-item checklist (Supplementary Table B1). Articles were given one point for each criterion met (10 possible points). The scale was adapted by excluding the therapist and assessor blinding criteria since blinding is not possible considering the nature of the AFO interventions [18]. Cross-over studies met the ‘blind allocation’ (3rd) criterion if participants were allocated to receive all conditions since assessor bias has no influence on group allocation if all participants received all interventions [18]. Additionally, studies that tested for stiffness effects between all AFO stiffness conditions met the ‘between-group statistics’ (8th) criterion, while papers that only compared with the baseline condition did not. The final (10th) criterion, adapted from a modified STROBE scale [23], was added to evaluate whether studies reported the test–retest reliability and/or accuracy of the devices and/or analyses used to measure AFO stiffness. Studies that utilized a pre-validated measurement method such as a three point bend test also met this criterion, while articles that did not report any quantitative stiffness measurements did not. When the three raters’ scores disagreed, a final score was reached by consensus.

3. Results

The database search yielded 287 non-duplicate scholarly articles and four additional articles were identified from other sources. After applying the exclusion criteria, this number decreased to 25 papers (Fig. 1). A majority of the studies received low to moderate methodological quality scores, below 8/10 (see Supplementary Table B2 for detailed scores). Only one study ensured subjects were blinded to the test conditions, only three specified sufficient participant eligibility criteria, 11 papers did not perform between-group statistical analyses, and 10 papers did not report the test re-test reliability of stiffness measurements. Eight of the 25 studies included only one to two participants and four studies had five to six participants.

The included papers tested a range of different populations including healthy adults (10 papers), adults with hemiplegia (11 papers), adults with severe lower limb trauma (including salvage) (2 papers), children with spastic hemiplegia (2 papers), and adults with Charcot-Marie-Tooth (CMT) disease (1 paper) (Table 1). They also included a variety of ankle foot orthosis designs including: passive dynamic AFOs [24,25,10,13,26,27], the Intrepid Dynamic Exoskeletal Orthosis (IDEO) with interchangeable posterior struts [28,20,29], off-the-shelf commercial braces [2], articulated AFOs with elastic bands [30,26], springs [31] or superelastic alloys [32,33], and custom hinged, experimental AFOs or exoskeletons made from metal or carbon fiber frames with steel springs [34,35,3,36–40], gas springs [41], oil-dampers [42,43], or modifiable Becker joints [44]. AFO stiffness was varied to test resistance to dorsiflexion (DF) only [27,30,35], plantarflexion (PF) only [34,26,43,36,37,3,38,41,39,40], DF and PF independently [42,44], or both DF and PF concurrently [25,24,26,28,31,45,2,29,10]. Two studies did not specify the direction of resistance [32,33]. All 25 analyzed papers used a crossover study design. In a majority, all subjects wore all AFO stiffness conditions while a variety of outcome measures were assessed (Table 2).

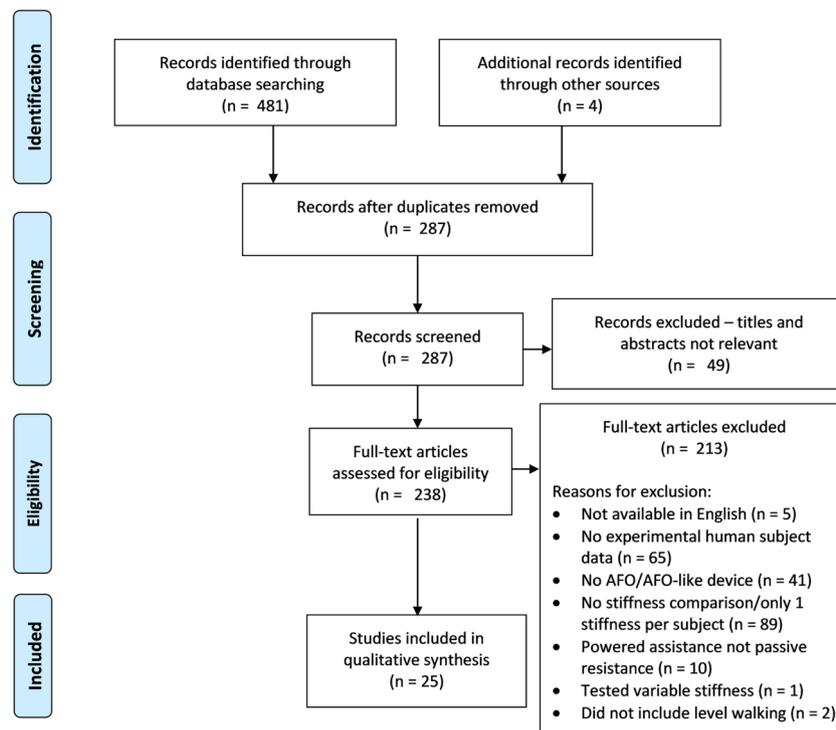


Fig. 1. PRISMA flow diagram of article search and selection process [21].

3.1. Quantifying AFO stiffness

The included studies differed in how they measured and reported AFO stiffness (Table 3). Stiffness was reported qualitatively in four [45,41,26,27] of 25 papers, estimated from finite element analyses in two papers [33,32], and quantified experimentally in 19 papers. Of the 19 that quantified stiffness experimentally, three used functional stiffness testing methods, where measurements are taken while the subject wears the AFO [46]. Another 13 assessed stiffness on the bench top. In this method, a mechanical testing machine records the load or torque as it performs a three-point bend test on the AFO's posterior strut [28] or flexes the AFO about the ankle in a custom fixture [3], respectively. Three studies did not specify the type of measurement method [40,39,38]. For each of these functional or bench top approaches, stiffness could be measured statically at one or more ankle flexion/extension positions or dynamically through the entire gait cycle or a specified range of motion.

Of the 21 studies that reported simulation-estimated or experimentally-measured stiffness, 19 reported AFO stiffness and two [28,29] only reported the linear stiffness of the compliant element at the joint (a posterior strut). Comparing studies that measured stiffness linearly with those measuring rotational stiffness was not possible. Moreover, when measuring rotational stiffness, some studies deflected the AFO towards plantarflexion or dorsiflexion only, while others tested both directions. Only eight of the 19 rotational stiffness papers directly provided quantitative stiffness values of their test conditions [2,25,24,30,35,31,42,38]. We were able to estimate AFO rotational stiffness in nine additional papers by fitting a line to torque versus angle curves or measurements provided. The included studies spanned a large range of AFO stiffness from 0.02 to 8.17 Nm/deg (Fig. 2).

Although all articles tested multiple AFO conditions, some study conditions may have had similar stiffness values [45]. This was only statistically compared in four studies. One study compared AFO stiffness measurements and found that one of three tested AFOs was not significantly different from the rest [2]. The other three studies evaluated peak AFO moment [30,3,35] and found significant differences across all test conditions.

3.2. AFO stiffness effects on joint kinematics

3.2.1. Ankle kinematics

Ankle kinematics were reported in 22 papers and 11 included statistical comparisons across different stiffnesses (Supplementary Table C1). Three studies reported a significant decrease in ankle range of motion (ROM) with increasing AFO stiffness (Fig. 3) [31,42,27]. Another three articles found decreased ROM but did not perform statistical analyses [34,32,33].

In addition to overall range of motion, several studies reported ankle angles at various points in the gait cycle. The ankle angle at initial contact was unaffected by AFO stiffness in one study in children with cerebral palsy [31], while two others found that the foot was more dorsiflexed at higher stiffnesses during initial contact in patients post-stroke [3,37]. This difference was not significant for all tested stiffnesses. The tendency toward increased dorsiflexion with increased stiffness (Fig. 3) was also reported as an untested observation in two additional studies of adults post-stroke [44,39].

Peak PF angle during early stance decreased with increasing stiffness [28,45,41,37,36,38]. This trend was significant for all stiffness conditions in one healthy-subject case study [41], and significant for a subset of stiffnesses in four papers [28,45,37,36]. An additional study observed the same trend, but did not perform statistical testing [38].

While peak dorsiflexion (DF), which typically occurs in terminal stance, generally decreased with increasing AFO stiffness (Fig. 3), the statistical findings were not consistent across studies. Changes in peak DF were significant across all stiffness conditions in three studies [42,27,30], significant for a subset of conditions in two studies [28,45], and not significant in one study [29]. The trend was also observed, but not statistically tested, in three case studies ($n = 1-2$) [34,44,25]. Comparisons of specific stiffnesses could not be made as only four studies reported quantitative AFO stiffness values [30,42,44,34]. Another case study reported a qualitative description of ankle kinematics under various stiffness conditions [10]. The subject had hemiplegia and a limited ankle DF range. As stiffness was gradually decreased, the subject's DF angle during terminal stance increased. Four studies statistically compared peak plantarflexion (PF) angle, which typically

Table 1
A summary of the participants and interventions included in the reviewed articles.

Paper	QS (0–10)	Participant details	Description of AFO stiffness intervention
Amerinatanz, 2016 [33]	5	1 healthy adult, age n/a	Unilateral articulated AFO that resisted ankle rotation (direction not specified) using one of two springs: a stainless steel spring and a superelastic nickel titanium spring
Amerinatanz, 2017 [32]	4	2 healthy adults (all male), 30–31 years	Unilateral articulated AFO that resisted ankle rotation (direction not specified) using one of two springs: a stainless steel spring and a superelastic nickel titanium spring
Arch, 2015 [25]	7	2 healthy adults (1 female), 24–25 years	Unilateral passive dynamic AFO that resisted both DF and PF at three stiffnesses that spanned about 35–80% of each subject's natural ankle pseudo-stiffness
Arch, 2016 [24]	6	2 healthy adults (1 female), 24–25 years	Unilateral passive dynamic AFO that resisted both DF and PF at two stiffnesses tuned to match about 40% and 80% of each subject's natural ankle pseudo-stiffness
Bolus, 2017 [34]	7	1 healthy adult (male), 23 yrs	Unilateral articulated, instrumented AFO (iAFO) that resisted PF using four different linear springs
Brunner, 1998 [27]	5	14 children with spastic hemiplegia (8 female), 6.5–20.1 years	Unilateral rigid and spring-type AFOs that resisted DF and blocked any PF
Choi, 2017 [30]	8	8 healthy adults (2 female), 25.3 (4.5) years	Unilateral articulated AFO that resisted DF using four different elastic bands
Collins, 2015 [35]	7	9 healthy adults (2 female), 23 (3.7) years	Bilateral exoskeleton that resisted DF using five different linear steel springs with a clutch
Guillebastre, 2009 [26]	7	11 healthy adults (5 female), 19–37 years	Unilateral rigid AFO that resisted both DF and PF and a dynamic AFO with an adjustable elastic band that only resisted PF at two stiffness conditions: 30% and 70% of maximal strain
Harper, 2014 [28]	7	13 adults with unilateral lower extremity injuries (all male), 21–40 years	Unilateral IDEO with three interchangeable, posteriorly mounted struts that resisted both DF and PF at each patient's prescribed stiffness and $\pm 20\%$ of prescribed
Kerkum, 2015 [31]	9	15 children with cerebral palsy (4 female), 6–14 years	Bilateral ($n = 14$)/unilateral ($n = 1$) spring-hinged ventral-shell AFO that resisted both DF and PF using different springs at three stiffness conditions (two of which had the same PF resistance but different DF resistances)
Kobayashi, 2011 [42]	6	10 adults post-stroke (all male), 46–62 years	Unilateral articulated AFO that resisted DF and PF independently using four oil-damper stiffness conditions ^a
Kobayashi, 2013 [43]	6	5 adults post-stroke (all male), 42–64 years	Unilateral articulated AFO that resisted PF using four oil-damper stiffness conditions
Kobayashi, 2015 [37]	6	10 adults post-stroke (2 female), 45–67 years ^b	Unilateral articulated AFO that resisted PF using three interchangeable steel springs and a baseline stiffness (close to zero) without springs
Kobayashi, 2016 [36]	6	6 adults post-stroke (all male), 38–64 years	Unilateral articulated AFO that resisted PF using three interchangeable steel springs and a baseline stiffness (close to zero) without springs
Kobayashi, 2017 [3]	6	10 adults post-stroke (2 female), 45–67 years ^b	Unilateral articulated AFO that resisted PF using three interchangeable steel springs and a baseline stiffness (close to zero) without springs
Kobayashi, 2017 [44]	5	1 adult post-stroke (female), 50 years	Unilateral articulated AFO that resisted DF and PF independently by adjusting the stiffness of a Becker Triple Action joint prototype to test four stiffnesses in each direction
Lehmann, 1983 [45]	5	6 adults with hemiplegia, 47–76 years and 4 healthy adults, 55–63 years	Unilateral thermoplastic AFOs (Engen and Teufel) at one trim and a unilateral polypropylene AFO (Seattle) at three trims that each resisted both DF and PF
Ramdharay, 2012 [2]	9	14 adults with CMT (5 female), 24–52 years	Bilateral footup splint, push brace and multfit achilles drop foot orthosis that each resisted both DF and PF at specific stiffnesses
Russell Esposito, 2014 [29]	8	13 adults with lower limb salvage (all male), 21–36 years	Unilateral IDEO with three interchangeable, posteriorly mounted struts that resisted both DF and PF at each patient's prescribed stiffness and $\pm 20\%$ of prescribed
Singer, 2014 [38]	5	5 adults post-stroke (2 female), 62 (9) years	Unilateral articulated AFO that resisted PF using two interchangeable compression springs
Sumiya, 1996 [10]	4	1 adult with hemiplegia (male), 55 years	Unilateral plastic AFO that resisted both DF and PF at nine stiffness levels achieved by gradually increasing the trimline depth from 20 to 60% of the lateral malleolus height
Telfer, 2012 [41]	5	1 healthy adult (male), 29 years	Unilateral articulated AFO that resisted PF using two posteriorly-attached gas springs with adjustable pressure to test two stiffness conditions
Yamamoto, 1993 [39]	2	15 adults with hemiplegia (4 female), 38–76 years	Unilateral articulated AFO that resisted PF using multiple combinations of four linear springs
Yamamoto, 1997 [40]	2	33 adults with hemiplegia, age n/a	Unilateral articulated AFO that resisted PF using different linear spring combinations to test four stiffness conditions

Acronyms: quality score (QS), dorsiflexion (DF), plantarflexion (PF), Charcot-Marie-Tooth disease (CMT), Intrepid Dynamic Exoskeletal Orthosis (IDEO).

^a During the PF resistance intervention, there was no DF resistance but during the DF resistance intervention, one of the PF resistance conditions were also selected and remained constant while DF resistance varied.

^b Studies [3,37] had the same test subjects.

occurs during initial swing, across stiffness conditions. Two studies found that peak PF significantly decreased with increasing stiffness for adults post-stroke [43,42], while the two others found no effect for adults with unilateral lower limb trauma [28,29]. An additional study with post-stroke patients also observed a decrease in PF but did not perform statistical testing [39]. A different healthy-subject case study [41] measured PF angle at toe-off and found significant differences across stiffnesses. Additionally, two studies compared ankle angle at foot clearance and found no statistically significant effects [2,29].

3.2.2. Knee kinematics

Fifteen studies reported knee kinematics and 10 included statistical comparisons between stiffness groups (Supplementary Table C2). One study measured knee range of motion and found no significant effects of

stiffness [29]. Others report knee angles at various points of phases in the gait cycle. Increased stiffness resulted in a more flexed knee at initial contact [37,3]. This effect was significant only for a subset of stiffness conditions including the least and most stiff conditions. There was a significant increase in early stance knee flexion with increasing stiffness in four studies [43,29,41,28], while three others reported no change [27,31] (Fig. 3). This effect was significant only for a subset of stiffness comparisons (including least and most stiff) in three of the studies [43,29,28], and significant for all stiffnesses in the fourth study of one healthy adult [41]. Two additional studies reported peak flexion in stance without statistical testing, and neither observed notable changes [44,38]. Peak knee extension during stance generally decreased with increased AFO stiffness (Fig. 3). This decrease was significant across all stiffnesses [30], significant across some stiffness

Table 2

The outcome measures collected in the reviewed studies. Further details are available in the supplementary material.

Paper	Joint Kinematics			Joint Kinetics			EMG	Walking Speed	Other Metrics
	Ankle	Knee	Hip	Ankle	Knee	Hip			
Amerinatanzi, 2016 [33]	✓			✓					
Amerinatanzi, 2017 [32]	✓			✓					GRF
Arch, 2015 [25]	✓			✓					Spatiotemporal
Arch, 2016 [24]				✓			✓		
Bolus, 2017 [34]	✓			✓					Center of pressure
Brunner, 1998 [27]	✓	✓	✓					✓	Spatiotemporal, GRF, arm swing
Choi, 2017 [30]	✓	✓	✓				✓		Muscle length
Collins, 2015 [35]	✓	✓	✓	✓	✓	✓	✓		Spatiotemporal, metabolics, COM power
Guillebastre, 2009 [26]								✓	Spatiotemporal, midline length
Harper, 2014 [28]	✓	✓	✓	✓	✓	✓	✓	✓	GRF
Kerkum, 2015 [31]	✓	✓	✓	✓	✓	✓		✓	Center of pressure, metabolics
Kobayashi, 2011 [42]	✓							✓	
Kobayashi, 2013 [43]	✓	✓						✓	
Kobayashi, 2015 [37]	✓	✓		✓	✓				
Kobayashi, 2016 [36]	✓	✓		✓	✓				
Kobayashi, 2017 [3]	✓	✓		✓					
Kobayashi, 2017 [44]	✓	✓		✓	✓				
Lehmann, 1983 [45]	✓								
Ramdharry, 2012 [2]	✓	✓	✓	✓		✓			
Russell Esposito, 2014 [29]	✓	✓	✓	✓	✓	✓		✓	Spatiotemporal, GRF, preference
Singer, 2014 [38]	✓	✓		✓	✓				
Sumiya, 1996 [10]	✓ [†]								
Telfer, 2012 [41]	✓	✓		✓	✓				
Yamamoto, 1993 [39]	✓	✓		✓					Spatiotemporal, preference
Yamamoto, 1997 [40]									Preference

Acronyms: double support (DS), single support (SS), center of mass (COM), ground reaction force (GRF).

[†]Only qualitative descriptions of ankle kinematics during gait are reported without quantitative measures.

conditions [36,37], and significant for only some participants [39] in different studies. Finally, there were no significant effects of stiffness on peak knee flexion during swing [28,43].

3.2.3. Hip and pelvis kinematics

Seven studies measured hip kinematics with five including statistical comparisons (Supplementary Table C3). In general, AFO stiffness did not have an effect on sagittal plane hip kinematics. Measures tested include hip ROM [29], peak hip flexion and extension during stance [29], peak hip flexion during swing [2,27], and the hip angle during the second double support phase [28] and contralateral initial contact [31].

Only two studies explored transverse and coronal plane hip motion. Brunner et al. found a small (< 1°), but significant decrease in

minimum hip abduction, but no change in external rotation for a rigid AFO compared to a “spring-like” one [27]. Neither study found an effect of stiffness on maximum hip abduction [27,2]. There was a significant decrease in minimum and maximum pelvic tilt [27], but no changes in pelvic rotation [27], obliquity [27], or elevation during swing [2].

3.3. AFO stiffness effects on kinetics

3.3.1. Ankle kinetics

In the 17 studies that reported ankle kinetics (Supplementary Table C4), there were few consistent significant effects of stiffness. Several studies measured peak PF and DF moments during gait. A majority

Table 3
Measurement method and value of AFO stiffnesses in the reviewed studies.

Paper	Method/sensor	AFO stiffnesses
Amerinatanzi, 2016 [33]	FES	Resistance to PF: 0.09, 0.24 Nm/deg/kg ^a
Amerinatanzi, 2017 [32]	FES, Bench/weights ^b	n/a ^c
Arch, 2015 [25]	Functional/forceplate	Resistance to DF: 1.90, 2.94, 3.51, 3.90, 5.77, 8.17 Nm/deg
Arch, 2016 [24]	Functional/forceplate	Resistance to DF: 1.90, 3.51, 3.90, 8.17 Nm/deg
Bolus, 2017 [34]	Bench/strain gauge	Resistance to DF or PF: 0.06, 0.15, 0.30, 0.35 Nm/deg ^{a,d}
Brunner, 1998 [27]	n/a	Gas spring pressure: 8–10 kPa (Spring-type), n/a (Rigid)
Choi, 2017 [30]	Bench/UTM ^e	Resistance to DF: 0.25, 1.0, 2.0, 3.7 Nm/deg
Collins, 2015 [35]	Bench/load cell	Resistance to DF: 2.27, 3.14, 4.19, 5.41, 6.98 Nm/deg
Guillebastre, 2009 [26]	n/a	n/a
Harper, 2014 [28]	Bench/UTM	Posterior strut stiffness: 402–1216 N/mm
Kerkum, 2015 [31]	Bench/BRUCE	Resistance to DF: 0.7 (0.2), 1.6 (0.4), 3.8 (0.7) Nm/deg; PF: 0.11 (0.13), 0.12 (0.17), 4.6 (1.3) Nm/deg
Kobayashi, 2011 [42]	Bench/torque meter	Resistance to DF and PF: 0.32, 0.41, 0.76, 1.26 Nm/deg
Kobayashi, 2013 [43]	Bench/MusCTM	Resistance to PF: 0.5–1.4 Nm/deg ^a
Kobayashi, 2015 [37]	Bench/torque sensor	Resistance to PF: 0.02, 0.28, 0.51, 0.58 Nm/deg ^a
Kobayashi, 2016 [36]	Bench/torque sensor	Resistance to PF: 0.02, 0.28, 0.51, 0.58 Nm/deg ^a
Kobayashi, 2017 [3]	Bench/torque sensor	Resistance to PF: 0.03, 0.16, 0.37, 0.48 Nm/deg ^a
Kobayashi, 2017 [44]	Bench/torque sensor	Resistance to DF: 1.41, 2.02, 2.88, 3.99 Nm/deg; PF: 0.36, 0.46, 0.52, 0.89 Nm/deg ^a
Lehmann, 1983 [45]	n/a	n/a
Ramdharry, 2012 [2]	Functional/isokinetic dynamometer	Resistance to DF: 0.92 (0.09), 1.11 (0.09), 1.17 (0.09) Nm/deg; PF: 0.59 (0.07), 0.87 (0.05), 0.89 (0.04) Nm/deg
Russell Esposito, 2014 [2]	Bench/UTM	Posterior strut stiffness: 392–1236 N/mm
Singer, 2014 [38]	n/a	Resistance to PF: 0.4, 1.3 Nm/deg
Sumiya, 1996 [10]	Bench/load cell	Resistance to PF: 0.40, 0.50, 0.63, 0.94, 1.13, 1.38, 1.73, 2.0, 2.25 Nm/deg; DF: 0.20, 0.23, 0.24, 0.25, 0.38, 0.48 Nm/deg ^a
Telfer, 2012 [41]	n/a	n/a
Yamamoto, 1993 [39]	(n/a)/load cell	Resistance to PF: 0.09, 0.19, 0.50, 1.0 Nm/deg ^{a,f}
Yamamoto, 1997 [40]	(n/a)/load cell	Resistance to PF: 0.5, 0.75, 1.25, 2.0 Nm/deg; DF: 0.5, 0.75, 1.5, 3.0 Nm/deg ^{a,d}

Acronyms: dorsiflexion (DF), plantarflexion (PF), finite element simulation (FES), universal testing machine (UTM), Bi-articular Reciprocal Universal Compliance Estimator (BRUCE) [52], muscle training machine (MusCTM).

^a Reviewers estimated stiffness by applying linear regressions to AFO torque and angle measurements.

^b Simulations were validated with experiments by hanging known weights on the AFO.

^c Linear fits were not possible.

^d AFO could be adjusted to independently resist PF/DF, but gait trials had PF resistance only.

^e A UTM measured linear stiffness, then AFO stiffness was calculated based on geometry.

^f Unspecified combinations of two springs were also used.

found that stiffness did not affect peak PF moment [29,28,31,41,35]. However, one study found that while net moment was not affected, peak biological PF moment (without the AFO contribution) significantly decreased with greater stiffness [35]. Peak DF moment during early stance was not significantly affected by stiffness in adults with CMT [2] or those with lower limb trauma [28,29]. In contrast,

three studies [36,37,39] of adults post-stroke, found a significant increase in DF moment. Two [36,37] of the three performed statistical comparisons against only the least stiff (near-zero) baseline condition. The only significant comparison was with the most stiff condition (a difference of one order of magnitude from about 0.02 Nm/deg to 0.58 Nm/deg). Singer et al. [38] also observed an increasing trend in

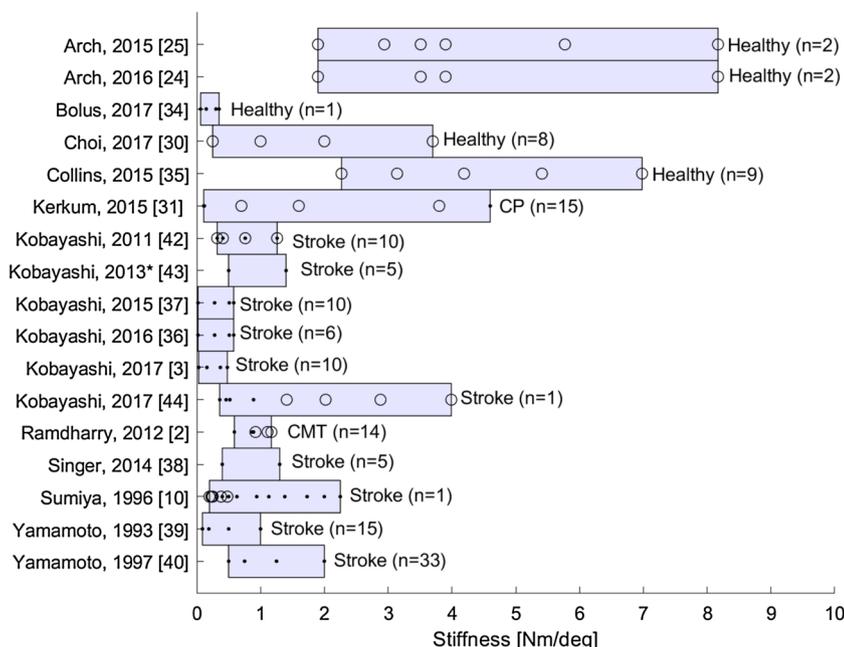


Fig. 2. The values and ranges of tested stiffness for the studies that reported, or included sufficient information to allow estimation of, stiffness in Nm/deg. The shaded region indicates the stiffness range, the open circles (o) are stiffnesses resisting dorsiflexion, and the dots (•) are stiffness values resisting plantarflexion. The subject population and number of participants are provided next to each study's stiffness range. *Study [43] only reported the range of tested stiffnesses.

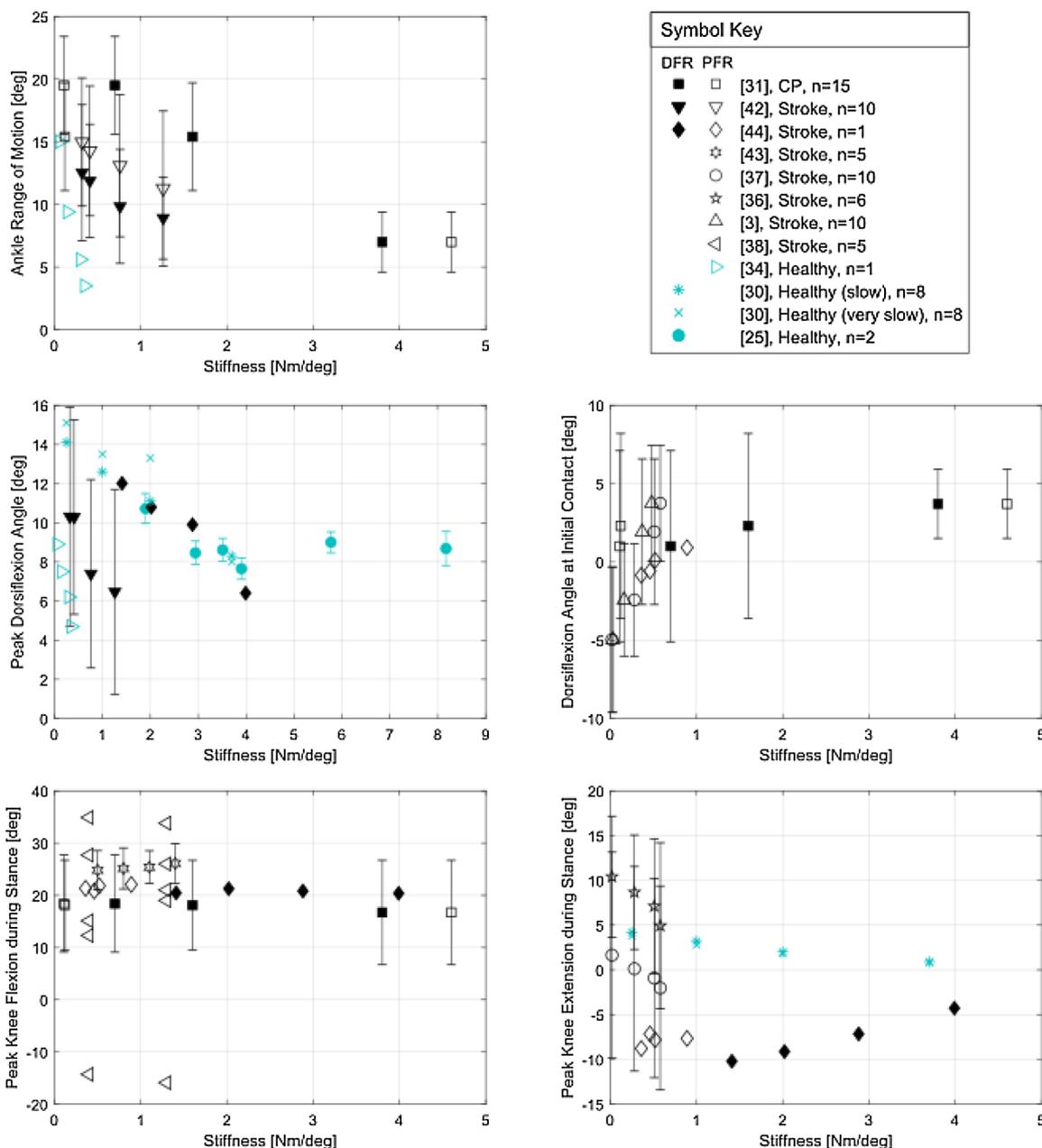


Fig. 3. Mean values of ankle and knee kinematics measures at the tested AFO stiffness interventions, which resisted dorsiflexion (DFR), plantarflexion (PFR) or both. The error bars represent ± 1 standard deviation from the mean. Median measures are plotted instead of means for study [30] at two different walking speeds (slow and very slow). Each subject's trial-means are plotted instead of across-subject means for studies [25] and [38]. Only the papers that provided stiffness in Nm/deg and corresponding kinematics measures at each stiffness level were included in this figure. The stiffness range provided in [43] was divided into five equally spaced stiffness values for plotting purposes.

patients post-stroke, but did not test statistical significance.

One study reported mechanical work [28] and a few others reported joint power during gait. Harper et al. [28] found that neither positive nor negative ankle work was significantly affected by stiffness. Two studies reported power absorption during stance. One found a significant decrease in average power absorption during a stride at greater stiffnesses [35], while the other found no differences in peak power absorption [29]. Peak power generation was reported in four studies, three of which performed statistical analyses with mixed results. Peak ankle power generation increased [31], decreased [2], or did not change [29] with greater AFO stiffnesses. Where there were differences, they were not seen across all tested stiffnesses. The fourth paper [44] was a case study, where increasing AFO resistance to DF resulted in reduced peak power generation, but increasing PF resistance had no

effect. Collins et al. reported average power generation, rather than peak. They found a significant decrease in power generation with greater DF resistance [35]. Finally, one paper found no effect for the timing of peak power generation during push-off [31].

3.3.2. Knee kinetics

Knee kinetics were reported in nine of the reviewed papers (Supplementary Table C5). Knee flexor moment typically has two peaks, one in early stance and another in late stance. Peak flexor moment was not affected by AFO stiffness in early stance [28], while results for terminal stance were mixed. Two studies conducted statistical comparisons across all tested stiffnesses and found no effects [28,29]. Another two studies [36,37] made comparisons only with the baseline (near-zero stiffness) condition and found a significant decrease in peak

moment with greater stiffness for a subset of stiffnesses. An additional case study [44] found increased peak flexor moment with greater PF resistance, but no changes for increased DF resistance. A final study averaged flexor moment across late stance and found a significant increase with greater stiffness [35]. An additional paper [31] reported knee moment at midstance (33% of the gait cycle) and found no effects. However, the same study [31] also measured knee flexor moment at the timing of peak knee extension angle during single support and found it increased with greater stiffness. The increase was only significant between the least and most stiff conditions.

Five studies measured peak knee extensor moment during stance. Of these, two performed statistical testing: one study found an increase in extensor moment at greater stiffnesses [47], while the other found no difference [28]. The increase was only significant between the most and least stiff conditions. Three different studies [38,41,44] also reported an increase in peak extensor moment, without statistical testing, only when resistance to plantarflexion (not dorsiflexion) was increased [44]. Another paper [35] calculated the average extensor moment during early stance, and found a significant decrease with greater stiffness.

One study [28] measured mechanical work and two others [29,35] reported knee power. Harper et al. [28] found that greater stiffness resulted in decreased negative work during first double support. This decrease was not significant for all stiffness conditions. Additionally, there was no effect of stiffness on knee power generation and absorption measured at various portions of the gait cycle [29,35].

3.3.3. Hip kinetics

Sagittal plane hip kinetics were measured in five studies [28,29,2,31,35]. There were no significant effects of stiffness on mean or peak hip moments, nor on peak hip power generation or absorption, during early or late stance (Supplementary Table C6).

3.3.4. Ground reaction force and center of pressure

Four studies measured ground reaction forces (GRFs) [28,29,32,27] and all except one study [32] performed statistical analyses (Supplementary Table C7). The majority of papers reported no significant effects of stiffness on vertical GRF at initial contact [28,27], minimum vertical GRF during stance [27], peak vertical GRF during early [28,29,27] and late stance [28,29], and peak propulsive and braking GRF [28,29,27]. However, Brunner et al. [27] found a significant reduction only in the 2nd peak of vertical GRF with a stiffer AFO in children with spastic hemiplegia. This study had a lower quality score (5/10) than the other two studies (scoring 7/10 and 8/10) that found no significant effects in the 2nd vertical peak in adults with lower limb trauma [28,29]. Additionally, the same two studies evaluated peak medial-lateral GRF and only one [28] found a significant increase, but only between the compliant and stiff strut conditions (40% difference). That study also observed the same trend for the sound (non-AFO) limb peak medial-lateral GRF [28].

Two studies measured the foot's center of pressure (CoP) during gait (see Supplementary Table C10 for details). Kerkum et al. [31] found that neither the excursion of CoP position during a step nor the CoP position at midstance was affected by AFO stiffness. Bolus et al. [34] noted a decrease in anterior displacement of the CoP as stiffness increased. No statistics were performed in that study.

3.4. AFO stiffness effects on spatiotemporal gait parameters

Ten studies measured spatiotemporal parameters (Supplementary Table C8) and found minimal or mixed effects of AFO stiffness. Self-selected walking speed was not affected [28,29,43,42,31] or decreased [27,26] with increased stiffness. The trend was not significant for all stiffness conditions [26]. AFO stiffness did not consistently affect step time [26] or stride time [29,39]. A majority of studies also found no effects on step length [26,25] or stride length [29,35]. In contrast, [27] found step and stride length decreased when AFO stiffness increased.

This effect was small (about 0.02–0.04 m decrease), however. There was no effect of AFO stiffness on stride width [29] or step width [35].

A few studies measured the time spent in various phases of the gait cycle. Two studies measured double support time: one found no changes [27], and the other performed within-subject comparisons and had mixed results [39]. Two studies reported single support time: one found a significant increase with greater stiffness [27] and the other had mixed results [39]. Another study found no significant effects for the percentage of gait spent in stance phase [26]. A healthy-subject case study ($n = 2$) also found that stance time remained generally consistent across stiffness conditions [25].

3.5. AFO stiffness effects on muscle activity and length

Muscle activity was only measured in four of the reviewed studies, one of which [24] did not perform statistical testing (Supplementary Table C9). The mostly commonly measured muscles were the gastrocnemius, soleus and tibialis anterior.

There is low evidence that ankle plantarflexor electromyography (EMG) is affected by AFO stiffness. One study found no effects for peak medial gastrocnemius (MG) activity during stance [30]. Another study found that the average integrated MG signal during late single-leg support decreased with increased stiffness [28]. The decrease was not significant for all stiffnesses. A third study found a significant increase for the combined medial and lateral gastrocnemius activity integrated over the whole stride [35]. The increase was not significant when the signal was integrated over the early stance to midstance region only. In addition to gastrocnemius muscle activity, one study reported muscle and tendon length and length velocity (Supplementary Table C10). Choi et al. [30] measured normalized lengths of the gastrocnemius musculotendon unit (MTU), achilles tendon (AT) and MG muscle, as well as muscle velocity (change in length per second) of the MG during the gait cycle in healthy adults. Increasing AFO stiffness caused statistically significant decreases in peak MTU and AT length during mid-terminal-stance, and increases in AT length at heel contact and in peak MG length. However, the effect was small (0.4–2.9% change). Normalized peak MG eccentric velocity was not affected. The time-integrated electromyographic signal (iEMG) of the soleus was not affected by stiffness in one study [28] and significantly decreased with stiffness in another [35].

Two studies compared ankle dorsiflexor activity. Collins et al. [35] found that tibialis anterior iEMG increased with increased AFO stiffness while Harper et al. [28] found no changes. Additionally, Harper et al. [28] found no significant stiffness effects on the gluteus medius, rectus femoris, biceps femoris long head, and vastus medialis iEMG signals during various regions of the gait cycle.

3.6. AFO stiffness effects on metabolic cost

Only two papers measured the effects of stiffness on metabolic cost [31,35]. Collins et al. [35] found a significant decrease and then increase in net metabolic cost as stiffness increased in healthy adults, with a minimum cost for moderate stiffness (3.14 Nm/deg). In contrast, Kerkum et al. [31] found no significant effects of AFO stiffness on metabolic cost in children with cerebral palsy. Collins et al. [35] increased dorsiflexion resistance from 2.27 to 6.98 Nm/deg, while Kerkum et al. varied resistance in both directions from 0.7 to 4.6 Nm/deg.

3.7. User preference

Three studies surveyed subject preference for particular stiffness conditions [29,39,40]. Results varied and there were no generalizable preferences among the different stiffness values tested (Supplementary Table C11). Moreover, one study [39], evaluating adults with hemiplegia, found no consistent correlations between a subject's preferred

stiffness and the stiffness at which they had optimal gait performance measures, including peak knee extension/flexion, peak dorsiflexion/plantarflexion moments, single support phase and second double support phase length.

3.8. Other collected metrics

Several studies reported outcomes we did not specifically include in our aims. These included: foot midline length [26], functional ankle joint stiffness [32], and arm swinging motion quality [27]. There were no significant effects for any of these measures. More details can be found in Supplementary Tables C10 and C11.

4. Discussion

We investigated the impact of the stiffness of ankle-foot orthoses (AFOs) on gait outcomes. The literature suggests that altering AFO stiffness mainly impacted kinematics directly at the ankle and, more proximally, at the knee. As the stiffness of the AFO increases, the user must generate a larger torque to deflect the AFO at the ankle. Thus, increased stiffness led to lower peak dorsiflexion and plantarflexion and consequently, decreased ankle range of motion. Stiff AFOs with increased plantarflexion resistance kept the foot in a more dorsiflexed position throughout gait, with some higher stiffnesses preventing any plantarflexion. Reduced plantarflexion counters the effects of functional drop foot, commonly found in people recovering from stroke [43,42] or those with spastic cerebral palsy [27]. It also promotes an initial contact with the heel rather than forefoot. Altered ankle mechanics resulted in compensations at the knee. There is moderate evidence that greater AFO stiffness results in increased knee flexion during stance. This effect was seen in both healthy unimpaired populations [30,41] and people with lower limb injuries [28,29] or those recovering from stroke [43]. As described in [43], an AFO that is too stiff can cause abrupt forward rotation of the tibia at initial contact causing the knee to be pushed forward, thereby increasing knee flexion at early stance and inducing gait instability. The addition of dorsiflexion resistance in conjunction with the plantarflexion stiffness, like in [31], prevents the tibia from collapsing over the foot and reduces the knee flexion effect.

AFO stiffness did not affect hip kinetics and there was low evidence for its effects on hip or pelvis kinematics, ankle or knee kinetics, muscle activity, metabolic cost, ground reaction forces or spatiotemporal parameters. Given the small number of available studies, we could not find sufficiently high evidence to support either the lack or presence of stiffness effects on these secondary outcome measures. It should be noted that the level and type of impairment may influence these findings. In particular, proximal muscle contractures may affect the extent to which proximal biomechanics can be normalized. As many of these studies included only healthy participants, these findings may not be applicable to individuals with impairments.

Self-selected walking speed (SWS) is a common clinical measure and is often used to gauge gait performance during patient evaluation and AFO fitting. There is low evidence that AFO stiffness affects walking speed. Walking speed was only significantly affected by stiffness in two of seven studies that measured it [27,26]. These studies found that people with cerebral palsy [27] and healthy adults [26] walked slower as AFO stiffness increased. Comparison of these two studies with the others is difficult as neither measured the actual stiffness of the AFOs they tested. However, SWS did improve (increase) with an AFO compared to barefoot walking [27].

In a recent review, Highsmith et al. suggested that stiffness should be considered with regard to user preference [20] as stiffness affected user preference more than it affected gait parameters. Only four of the reviewed articles evaluated patient preference. The results were varied with no generalizable patterns. Only one study investigated outcomes at the preferred stiffness compared to the other stiffness conditions [39]. Yamamoto et al. found that the stiffness selected by each subject

did not necessarily coincide with the stiffness at which maximum dorsiflexion corrective moment was generated [39]. Therefore, there is insufficient evidence to establish a relationship between patient preference and quantitative measures of gait performance. Future work should focus on understanding what factors drive user preferences and whether preferred stiffnesses result in improved gait mechanics.

In general, it was difficult to draw comparisons between studies when trends differed due to differences in how stiffness was measured or reported. Because of this, we were unable to achieve our secondary aim of determining the stiffness ranges that impact walking mechanics. Other reviews exploring AFO design parameters also note both the lack of sufficient detail in AFO design descriptions [48] and inconsistency of measurement techniques [46]. AFO ankle stiffness, in particular, may be less frequently reported since there are no commercially available tools or standardized procedures to measure it. As such, research groups must create and validate their own testing devices. Accordingly, many did not test AFO stiffness, with some measuring only linear stiffness of the posterior strut [28,29] and others reporting nothing at all [41,45,26]. A few studies utilized *functional* measurement methods, where it was unclear whether the reported stiffness was that of the AFO alone or the AFO with the biologic ankle. Only about half of the reviewed studies reported both AFO stiffness and the test–retest reliability of their measurement method (Supplementary Table B2). Additionally, the direction and speed at which the AFO was deflected during stiffness testing was inconsistent across studies. While velocity effects are not significant for thermoplastic AFOs [49,50], the effect on other materials such as printed composites remains unknown. Finally, in some cases, AFOs were chosen by type, with the assumption that one would be stiffer than another. However, one study that statistically compared the stiffnesses of the various devices it tested, found that the actual stiffness did not differ between some of the AFOs [2]. Thus, it is possible that not all conditions included here had uniquely different stiffnesses.

In this review, we utilized the standard approximation of stiffness as the slope of a linear regression through the AFO's torque–angle curve. However, many AFOs have a hysteretic torque–angle curve due to their viscoelastic properties; the torque required to flex the AFO to a specific angle is not equal to the torque generated when it is released. Thus, a description that also includes the regression intercept, width of the curve, and/or area inside the hysteresis loop [49] may be a better representation of the AFO's energy storage and dissipation properties.

It is likely that stiffness effects would differ depending on the deficits of a particular population. The current literature has an insufficient number of high quality articles that evaluated the same clinical population under similar stiffness interventions and using the same outcome measures for us to make meaningful conclusions. Most of the articles had low to moderate quality rating scores (below 7/10); many did not provide sufficient participant eligibility details or perform between-group statistical analyses across stiffness conditions. A third of the articles were case studies of one to two individuals. About half of the reviewed studies tested individuals recovering from stroke but had inconsistent stiffness ranges resisting plantarflexion, dorsiflexion or both (Fig. 2). Differences in reported outcome measures between the studies also made comparisons challenging. Similar challenges were noted in a review by Chisholm [7].

There were several possible confounding factors in the reviewed studies. First, we only considered AFO stiffness at the ankle joint in the sagittal plane. It is possible that other factors such as lateral or torsional stiffness of the AFO or compliance of the footplate impacted the findings across different studies. The profile and shape of the sole as well as the pitch, i.e. the height of the sole at the heel relative to at the toe, of the AFO or AFO-footwear combination may also impact user comfort and outcomes. Sole profile plays a key role in the timing of knee flexion during pre-swing. A higher pitch AFO-footwear combination would increase plantarflexion during midstance. For individuals with gastrocnemius contractures, if the increased plantarflexion is insufficient, the contracture might limit the user's ability to extend the knee. Second, we

did not consider the shank to vertical angle of the studied AFOs as it was often not provided. This angle affects where the AFO stiffness (torque versus angle) curve intersects the horizontal axis. The shank to vertical angle likely affects the timing of AFO PF or DF resistance during the gait cycle, thus affecting several parameters including where the ground reaction force vector passes through the knee during midstance. Third, the acclimation period for different conditions differed between studies, with a majority testing all conditions in a single session. Longer accommodation periods may affect outcomes differently. Fourth, the user's walking speed may have affected stiffness comparisons. The included articles required participants to walk either at a self-selected or predetermined walking speed. Joint kinematics and kinetics are impacted by walking speed and thus any changes might be the result of speed rather than stiffness. However, self-selected speed was only affected in two studies [27,26]. In addition, the impact of stiffness may be different at different speeds. One study [30] evaluated the impact of stiffness separately at slow and very slow walking speeds and did not find differences. The study included only healthy adults who would choose to walk much faster. The impact may be different for clinical populations or at faster walking speeds. Finally, the available literature is not sufficient to determine whether other activities, such as running [47] or walking on an incline [51], are impacted differently than level-walking by AFO stiffness.

5. Conclusion

This review found sufficient evidence to indicate that increasing AFO stiffness decreases ankle range of motion and increases stance knee flexion during gait. There was low evidence for the effect of stiffness on other outcome measures including hip mechanics, muscle activity and metabolics. However, differences in measured outcomes, subject populations and stiffness reporting made determining the influence of AFO stiffness on walking performance difficult. Standardized stiffness testing and reporting guidelines should be established to ensure AFO device characteristics are sufficiently communicated and allow comparison across studies. Based on this review, we suggest the following guidelines for future studies: (1) Researchers should provide the type, material, pitch, manufacturing method and torque–angle curve for each AFO used. They should also cite the measurement instrument and technique used to obtain those curves. (2) AFO stiffness should be measured in both plantarflexion and dorsiflexion directions and the speed of flexion testing should be reported. (3) Participants should be tested at both a prescribed walking speed and preferred speed to facilitate inter-subject comparisons. (4) Detailed descriptions of subject characteristics should be provided, including noting any contractures. (5) Each subject's raw data, including preferred walking speed, rather than across-subject averages should be provided to allow deeper analyses for individual stiffness effects. (6) Considering AFO-footwear interaction effects, authors should note the type, make and model of the footwear used with the AFO. When possible, we recommend standardizing footwear across participants. With future studies providing this level of detail we can better understand the effects of a wide range of stiffnesses on specific populations, and thus improve patient outcomes.

Conflicts of interest

None.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the

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