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Systematic Review

The Role of Ankle–Foot Orthoses in Improving Gait in Children and Adolescents with Neuromotor Disability: A Systematic Review and Meta-Analysis

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Abstract: Background/Objectives: International guidelines recommend the use of orthoses in subjects with cerebral palsy (CP), even though there is limited evidence of their effectiveness. Little is known about their effectiveness in children and adolescents with other types of neuromotor disability. Methods: The review protocol was recorded on the PROSPERO register (CRD42024509165) and conformed to the PRISMA guidelines. The inclusion criteria were any type of ankle–foot orthoses (AFOs); pediatric subjects with any non-acquired neuromotor disease; any type of outcome measure regarding gait performance; controlled studies; and those in the English language. Screening, selection, risk of bias assessment, and data extraction were performed by a group of independent researchers. Results: Fifty-seven reports were included, with most regarding CP; three involved subjects with Charcot–Marie–Tooth disease or Duchenne dystrophy. Nine were RCTs. A meta-analysis was performed for studies including subjects with CP. The meta-analysis demonstrated the effectiveness of AFOs in increasing stride length (MD −10.21 [−13.92, −6.51]), ankle dorsiflexion at IC (MD 9.66 [7.05, 12.27]), and peak ankle DF in stance (MD 5.72 [2.34, 9.09]) while reducing cadence (MD 0.13 [0.06, 0.17]) and the energy cost of walking (MD −0.02 [−0.03, −0.00]). The peak ankle power generated at push-off was significantly increased with flexible AFOs compared to rigid AFOs (MD 0.38 [0.30, 0.46]), but it decreased with both compared to walking barefoot or with shoes (MD −0.35 [−0.49, −0.22]). Evidence regarding DMD and CMT was limited but suggested opting for individualized flexible AFOs, which preserved peak ankle power generation. Conclusions: AFOs improve gait performance in CP. Flexible AFOs are preferable because they preserve the peak ankle power generated at push-off compared to rigid AFOs.

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1. Introduction

Australian CPG [1] guidelines and Italian care pathways [2] recommend the use of orthoses (either functional or positional) in patients with cerebral palsy, even though both declare that there is limited evidence of their effectiveness. Previous systematic reviews (SRs) have explored the role of orthoses in improving gait and gross motor performance in patients with cerebral palsy. Aboutarabi et al. [3] reviewed studies on gait improvement in patients with cerebral palsy walking with ankle–foot orthoses (AFOs), but the search was limited to 2007–2015. Lintanf et al. [4] extended the search to 2018 and reported significant improvements in spatial–temporal parameters (speed, step length, and cadence) and ankle dorsiflexion at initial contact and in the swing phase. Betancourt et al. [5] reviewed only prospective controlled studies published between 2001 and 2016, restricted to a minimum sample of 20 patients for non-randomized and 10 patients for randomized trials. The interventions were limited to rigid or articulated AFOs versus barefoot or shoes only as a control condition.

A recent SR by Miccinilli et al. [6] studied the literature published in 2006–2022, focusing on randomized controlled trials regarding ankle–foot or knee–ankle–foot orthoses in pediatric patients with cerebral palsy. Nonetheless, the authors included among the outcomes several outcomes beyond gait, such as trunk control, balance, the prevention of muscle contractures, and quality of life. Furthermore, most of the included studies used orthoses combined with other treatments.

In general, improvements in spatial–temporal parameters and energy expenditure are reported, but evidence specifically relating to the influence of AFOs on gait parameters needs to be updated. Furthermore, we were interested in extending this SR to other neurologic disorders limiting walking performance in children and adolescents. Similar biomechanic problems and gait patterns might occur in different pathologies, which might, hence, share the same type of orthotic approach. For this reason, we were interested in studying the role of AFOs not limited to CP and were open to the possibility of finding studies with mixed health conditions. Therefore, we performed an SR inquiring about the role of any type of ankle–foot orthoses in modifying gait performance in children or adolescents diagnosed with a neurological disease inducing motor disability.

2. Materials and Methods

The present study is a systematic review of primary studies performed according to the reporting guidelines of the PRISMA statement [7] and Cochrane's methodological recommendation [8]. The review protocol was recorded on the PROSPERO public online register (CRD42024509165). This study was conducted according to the pre-specified protocol, except for the inclusion–exclusion criteria that were modified, limiting inclusion to controlled studies (retrospective or prospective) and excluding any other type of study; in addition, a meta-analysis was performed.

The scope of this systematic review was structured according to the PICO (patients, intervention, control, outcome) framework for intervention:

- P: children and adolescents (age 0–18 years) with neurological disease such as cerebral palsy or neuromuscular disease or spina bifida (excluding orthopedic diseases, cancer, and acquired brain injuries);

- I: the use of any type of functional ankle–foot orthoses (solid, hinged, carbon leaf, etc.);
- C: no treatment or any other treatment;
- O: a change in walking performance, measured by means of any gait parameter or outcome measure to assess gait improvement after intervention, such as velocity, stride length, or any other three-dimensional gait analysis parameter, 6 min walk test (6 MWT), or 10 m walk test (10 MWT).

The search procedures are described in Supplementary Table S1. A literature search was performed on 11 August 2023 in the following databases: PubMed, Scopus, and Cinahl. Articles were searched without limits on the year of publication, age, or language. A limit was introduced regarding the type of study, with systematic reviews, guidelines, and animal studies being excluded. Non-controlled studies, publications with samples involving adult patients, and papers in languages other than English or Italian were also excluded. Other articles were also obtained from the reference lists of the papers identified through the primary search in the databases.

According to these inclusion and exclusion criteria, all the studies were screened firstly by title/abstract and then by full text by two independent authors (SF, EV, EP, GC, FM, GT, IT, and AE). Any disagreement was resolved through discussion among the authors. Non-retrieved papers and ongoing studies were just recorded as not retrieved.

2.1. Data Extraction

Two authors independently completed the data extraction (SF, GT, IT, and AE). The authors extracted data about the study design and methodology, participant characteristics, protocol details, outcome measures, and results of the studies. Any disagreement among the authors was discussed and resolved by consensus.

2.2. Risk of Bias Assessment

The risk of bias (RoB) was assessed with a domain-based approach using the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) [9,10] tool in controlled studies and using version 2 of the Cochrane risk-of-bias (ROB2) tool for RCTs (specific for a cross-over design) [11,12]. Two independent reviewers (SF, GT, IT, and AE) assessed the methodological quality and risk of bias of all the included studies. Any disagreement was resolved through discussion among the authors. The assessment of the RoB did not provide criteria for excluding articles but allowed for stratifying them.

2.3. Meta-Analysis

A meta-analysis was performed to pool studies reporting comparable outcomes.

Each type of ankle–foot orthosis (AFO) was compared to the control condition (barefoot or shoes), except for the outcome "peak ankle power in pre-swing", where an additional comparison between rigid and flexible AFOs was carried out. The heterogeneity was investigated using the I^2 test. The source of heterogeneity was investigated when appropriate. For continuous outcomes, mean differences (MDs) and their 95% confidence intervals (CIs) were calculated using the inverse variance method according to a random-effects model. For the outcomes stride length and energy cost at self-selected speed, the data were converted to a uniform unit of measurement. The pooled estimates are presented as overall and stratified by AFO type (rigid and flexible). Statistical analyses were conducted using Stata 18 software [13].

3. Results

After full text analysis, 57 studies were finally included in the review [14–70]. Figure 1 provides details about the study identification and selection (PRISMA flow diagram).

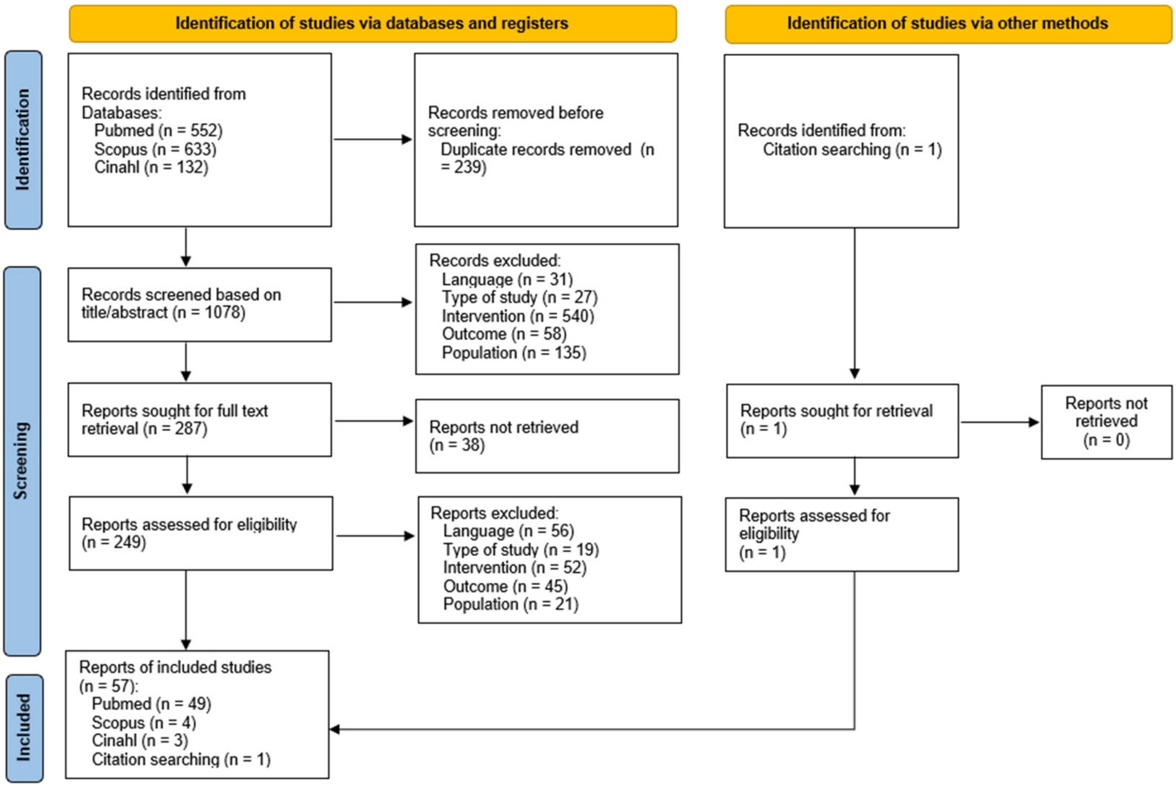

Figure 1. PRISMA flow diagram.

3.1. Risk of Bias of Included Studies

An overall synthesis of the RoB of the included studies is represented in Figures 2 and 3. Samples including a wide age range, mixed gross motor functioning levels, mixed diagnoses, and combined interventions were considered to have confounding factors. Furthermore, a lack of time interval between the gait analysis assessment in different conditions was included as a possible confounding aspect, because of the possibility of fatigue influencing the second assessment. The overall quality of non-randomized studies was low, while only some concerns were attributed to RCTs. The study by Meins et al. [67] presents bias in the selection of the reported results because the authors describe secondary results of a previously published RCT [66].

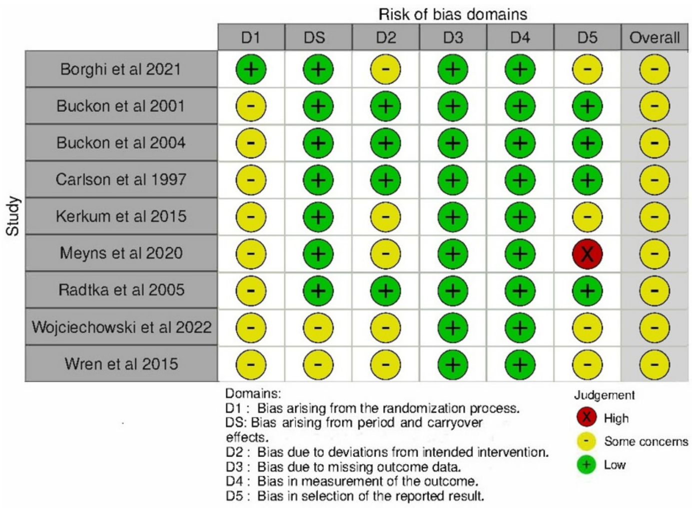

Figure 2. Risk of bias of RCT intervention studies: ROB2 plot [62–70].

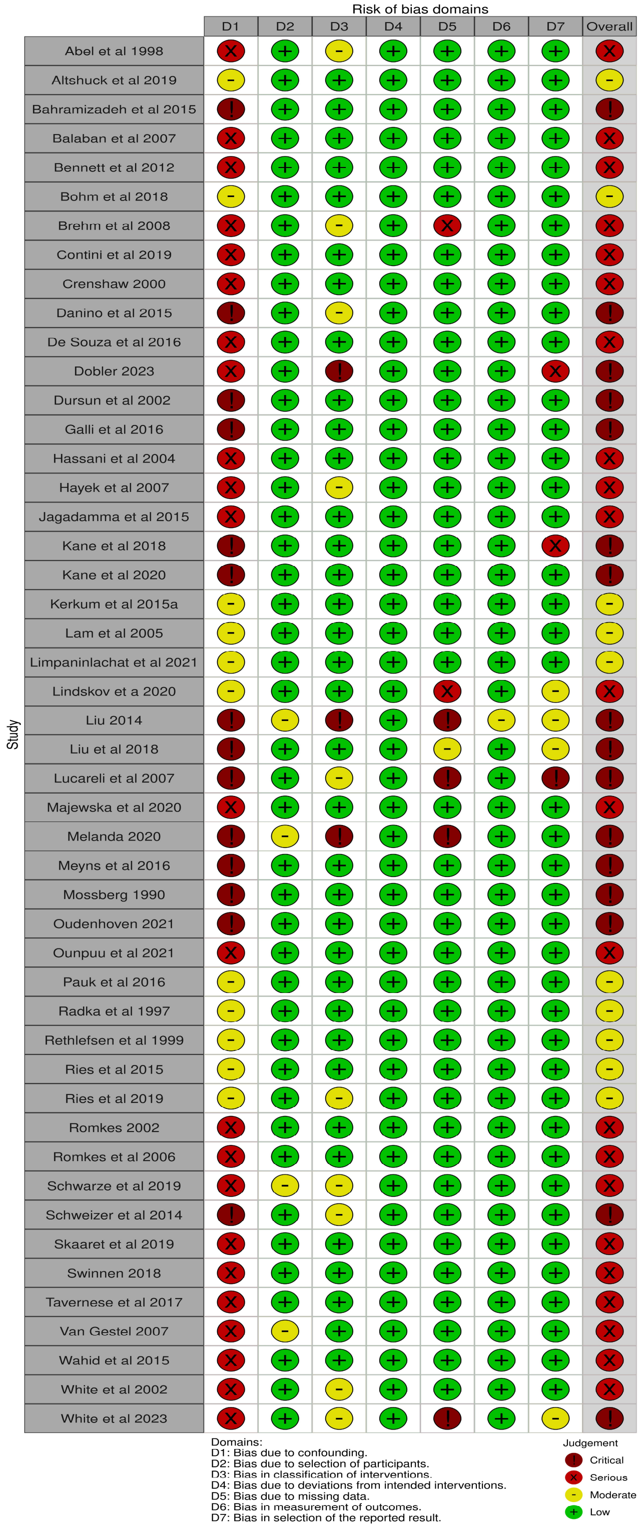

Figure 3. Risk of bias of non-controlled studies: ROBINS-I plot [14–61].

3.2. Evidence Synthesis

Several types of AFO were explored in the included studies. Solid or fixed AFOs [18,20,21,23,31,32,35,37,38,45,47–50,57,59–61,63,64,68] and rigid ventral shell AFOs (vAFOs) [33,66,67] were described as solid AFOs (SAFOs). Furthermore, different types of flexible AFOs were proposed: dynamic AFO (DAFO) [23,27,28,34,47,51,53,70]; hinged ankle–foot orthosis (HAFO) [17,18,21–23,27,28,31,35,37,38,41,42,44,45,48,49,51,52,54,55,60–64,68]; hinged ankle–foot orthosis with a contoured footplate (HAFOc) [36]; hinged ankle–

foot orthosis with a flatter, unmodified footplate (HAFOf) [36]; adjustable dynamic response AFO (ADRAFO) [70]; carbon-composite ankle–foot orthoses (c-AFO) [15]; carbon modular orthosis (CAMO) [31,57]; carbon-fiber AFO Ankle Seven (CAFO) [62]; dual carbon fiber spring AFO (CFO) [58]; DAFO with dynamic, elastic shank adaptation (DESA) [53]; tone reducing AFO (TRAFO) [22]; stiff and flexible vAFO [66,67]; ground (or floor) reaction force ankle–foot orthosis (GRAFO) [19,39,45,50,53,55]; modified GRAFO (mGRAFO) [16]; instantaneously adjustable alignment ankle–foot orthosis (iAA-AFO) [32]; orthosis with the dorsal part containing 11 sleeves (Orteams®) [58]; posterior leaf spring (PLS) [20,23,31,40,44,45,49,56,58,63,64]; supramalleolar orthosis (SMO) [22,31,37,38,65]. Multiple comparisons were performed either between different types of AFO or with walking barefoot or with shoes.

Most of the studies focused on patients with cerebral palsy, except three.

The only study that investigated children with DMD (20 subjects, aged 4–12 years) compared two groups walking with shoes or with AFOs [24]. Furthermore, five children were re-assessed after a 6-month period of night-time AFO use. The results are limited by the small sample and non-randomized protocol. The authors interestingly suggested that both daytime and night-time use of AFOs minimized typical compensations to equinus observed in the DMD gait pattern. Nonetheless, daytime AFOs reduced the ankle power generation at pre swing.

Two studies assessed the role of AFOs in patients affected by Charcot–Marie–Tooth (CMT) disease. An RCT [69] involved 12 children with mixed CMT types (types 1A, 1E, 2, 2D, 4, and X3) and mixed foot deformities (cavovarus, neutral, and planovalgus). The authors compared the effectiveness of mixed types of traditional or 3D-printed AFOs (PLF, HAFO, and SAFO) with shoes only. All the types of AFOs restored the DF at initial contact and maximum ankle plantarflexion moment in stance, reduced the peak pressure beneath the foot, and resulted in similar scores in the Client Satisfaction with Device module of the Orthotics and Prosthetics Users' Survey. Compared to traditional AFOs, 3D-printed redesigned AFOs increased the maximum ankle plantarflexion at push-off because of their improved flexibility. A non-randomized cross-over study [45] involved 15 children with mixed-type CMT (1, 2, 4E, and unknown) and compared the gait performance with individualized AFOs (PLF, HAFO, and SAFO) and barefoot. Like in the previous RCT, improvements were observed in patients with increased equinus in swing, but the AFOs did not provide enough support in patients with increased dorsiflexion in the terminal stance.

The age range was generally wide within most of the studies, extending from children to young adults: this was considered to pose an RoB.

The outcome measures, related to gait performance, included three-dimensional gait analysis (3DGA) parameters, such as kinematics; kinetics; electromyography (EMG); spatial–temporal parameters (STPs); derived indexes, such as the gait variability index (GVI), gait deviation index (GDI), and gait profile index (GPI); and energy cost.

The characteristics of the included RCTs and non-randomized prospective or retrospective studies are represented in Table 1 and Supplementary Table S2, respectively. The outcome measures are described, but only statistically significant results are reported. The level of significance was 5% for all the studies ($p < 0.05$), except for the study by Swinnen et al. (2018) [56], where the authors considered a level of significance of 10% ($p < 0.10$).

Table 1. Characteristics of included randomized controlled trials.

References	Study Design	Population	Mean Age	Diagnosis	Level of Functioning	Usage Period	Comparisons	Outcomes	Results
Borghi C. et al., 2021 [62]	RCT crossover	10 (5 M, 5 F)	11.5 ± 4	DCP	GMFCS: II	4 wk	HAFO vs. CAFO	3DGA: ankle pw generation, KEn in St	Energy produced (J/kg): HAFO 6.9 IQR 5, CAFO 9.5 IQR 7.8 Energy absorbed (J/kg): HAFO 17.4 IQR 7.4, CAFO 13.8 IQR 8.3
Buckon CE et al., 2001 [63]	RCT crossover	30, 21 M and 9 F	9.4 range 5–15 yrs	HCP	Unsp	3 mo no AFO − 3 random sequences of SAFO/HAFO/PLS, for 3 mo each	BF vs. SAFO vs. HAFO vs. PLS	3DGA: kinematics, kinetics, STP; oxygen consumption, WEC; BOTMP, GMFM, PEDI	DF at IC (°): SAFO 2 ± 4, HAFO 3 ± 4, PLS −0.2 ± 5, BF −11 ± 6 Peak DF in ST (°): HAFO 16 ± 6, SAFO 11 ± 5, PLS 13 ± 7, BF 6 ± 5 Dynamic ankle range (°): HAFO 16 ± 4, SAFO 11 ± 3, PLS 15 ± 4, BF 26 ± 7 Peak ankle pw in ST (W/kg): SAFO 0.88 ± 0.30, HAFO 1.24 ± 0.35, PLS 1.15 ± 0.29, BF 1.41 ± 0.51 sl (m): HAFO 0.57 ± 0.09, SAFO 0.57 ± 0.10, PLS 0.59 ± 0.09, BF 0.50 ± 0.10 SL (m): HAFO 1.18 ± 0.17, SAFO 1.14 ± 0.17, PLS 1.19 ± 0.15, BF 1.01 ± 0.18 Cad (steps/min): HAFO 117 ±14, SAFO 117 ± 12, PLS 119 ± 16, BF 127 ± 17 WEC self-selected ws (J/kg): SAFO 0.258 ± 0.05, HAFO 0.257 ± 0.07, PLS 0.264 ± 0.05, BF.276 ± 0.05 WEC fast walking (J/kg): SAFO 0.259 ± 0.05, HAFO 0.250 ± 0.07, PLS 0.264 ± 0.06, BF.279 ± 0.05

Table 1. *Cont.*

References	Study Design	Population	Mean Age	Diagnosis	Level of Functioning	Usage Period	Comparisons	Outcomes	Results
Buckon CE et al., 2004 [64]	RCT crossover	16, 10 M and 6 F	8.4 ± 2.4 yrs	SDCP	GMCFS: I (4 pt)–II (12 pt)	3 mo no AFO − 3 random sequences of SAFO/HAFO/PLS, for 3 mo each	BF vs. SAFO vs. HAFO vs. PLS	3DGA: kinematics, kinetics, STP; oxygen consumption, WEC; BOTMP, GMFM, PEDI	Minimum pelvic tilt (°): HAFO 13.5 ± 7, PLS 16 ± 6.9, SAFO 13.4 ± 6.9, BF 14.7 ± 4.3 Minimum HF (°): HAFO 0.5 ± 7.6, PLS 3.1 ± 8.6, SAFO −0.7 ± 9.7, BF 2.6 ± 9.4 DF at IC (°): HAFO 5.4 ± 3.9, PLS 4.8 ± 4.6, SAFO 5 ± 4.5, BF −7.2 ± 13 Peak DF in ST (°): HAFO 18.6 ± 8.3, PLS 14.8 ± 7.3, SAFO 12.5 ± 5.3°, BF 5.7 ± 12.9 Peak DF time (%): HAFO 46 ± 5, PLS 38 ± 13, SAFO 36 ± 13, BF 27 ± 14 Peak DF in SW (°): HAFO 8.3 ± 5.5, PLS 6.9 ± 4.6, SAFO 7.2 ± 5.6, BF –3.6 ± 13.9 Peak KE moment early stance (Nm(kg): HAFO 0.54 ± 0.28, BF 0.33 ± 0.32 Peak DF moment early ST (Nm/kg): HAFO –0.11 ± 0.09, PLS –0.13 ± 0.12, SAFO –0.11 ± 0.09, BF 0.01 ± 0.03 Peak ankle pw in ST (W/kg): HAFO 1.18 ± 0.31, PLS 1.23 ± 0.45, SAFO 0.83 ± 0.17, BF 1.59 ± 0.51 sl (m): HAFO 0.50 ± 0.10, PLS 0.54 ± 0.08, SAFO 0.51 ± 0.10, BF 0.45 ± 0.08 SL (m): HAFO 0.99 ± 0.18, PLS 1.05 ± 0.15, SAFO 1.02 ± 0.18, BF 0.91 ± 0.15 Cad (steps/min): HAFO 118 ± 14, PLS 127 ± 22, SAFO 124 ± 15, BF 142 ± 23 WEC self-selected ws (mLO_2/Kg/m): HAFO 0.363 ± 0.09, PLS 0.368 ± 0.08, SAFO 0.353 ± 0.09, BF 0.417 ± 0.11 WEC fast ws (mLO_2/Kg/m): HAFO 0.360 ± 0.08, PLS 0.352 ± 0.08, SAFO 0.338 ± 0.07, BF 0.398 ± 0.10 BOTMP UL coordination: HAFO 13.5 ± 5.4, PLS 13.9 ± 5.7, SAFO 14.9 ± 4.4, BF 11.9 ± 5.6 BOTMP UL speed&dexterity: HAFO 28 ± 10.1, PLS 28.1 ± 10.7, SAFO 28.0 ± 8.8, BF 26.2 ±9.1 GMFM walking/running/jumping: HAFO 61 ± 10.9, PLS 60.8 ± 10.3, SAFO 60.6 ± 10.5, BF 57.1 ± 12

Table 1. *Cont.*

References	Study Design	Population	Mean Age	Diagnosis	Level of Functioning	Usage Period	Comparisons	Outcomes	Results
Carlson WE et al., 1997 [65]	RCT crossover	11, 6 M and 5 F	6.9 ± 2.19 yrs	SDCP	Unsp	1 mo no AFO − 1 mo AFO or SMO − 1 mo no AFO − 1 mo AFO or SMO	AFO vs. SMO vs. BF	3DGA: kinematics, kinetics, STP	Sagittal ankle ROM (°): 1st baseline 26.1 ± 6.6, AFO 11.9 ±3.4, 2nd baseline 24.6 ±4.4, SMO 25.4 ±6.4 Peak DF at IC (°): 1st baseline 3.8 ± 6.6, AFO 10 ±6, 2nd baseline 1.8 ±6.7, SMO 3.3 ±7 Peak ankle PF moment (Nm/kg): 1st baseline 0.85 ± 0.13, AFO 1.02 ± 0.19, 2nd baseline 0.87 ± 0.12, SMO 0.94 ± 0.11 Peak ankle pw in pSW (W/kg): 1st baseline 1.35 ± 0.35, AFO 1.05 ± 0.37, 2nd baseline 1.50 ± 0.54, SMO 1.64 ± 0.61
Kerkum YL et al., 2015b [66]	RCT crossover AFO-CP trial	15, 11 M, 4 F	10 ± 2 yrs, range 6–14 yrs	SCP	GMFCS: 2 level I, 11 level II, 2 level III	acclimatization period of 4 wk for each level of stiffness	Three level of stiffness (flexible, stiff, rigid) vAFO vs. shoes	3DGA: kinematics, kinetics, STP, WEC	Speed (m/s): rigid 1.07, stiff 1.00, flexible 1.05, shoes 1.09 Peak KE in MSt (°): rigid 16.7 ± 10.0, stiff 18.1 ± 8.6, flexible 18.4 ± 9.3, shoes 22.7 ± 8.7 Peak KE moment in MSt (Nm/kg): rigid −0.15 ± 0.17, stiff −0.12 ± 0.15, flexible −0.07 ± 0.16, shoes 0.08 ± 0.15 Ankle RoM in stride (°): rigid 7.0 ± 2.4, stiff 15.4 ± 4.3, flexible 19.5 ± 3.9, shoes 35.4 ± 8.1 DF at IC (°): rigid 3.7 ± 2.2, stiff 2.3 ± 5.9, flexible 1.0 ± 6.1, shoes −2.6 ± 7.6 DF in MSt (°): rigid 7.9 ± 2.6, stiff 9.1 ± 5.1, flexible 9.4 ± 6.1, shoes 11.4 ± 8.4 Peak PF ankle moment in ST (Nm/kg): rigid 1.21 ± 0.18, stiff 1.21 ± 0.18, flexible 1.19 ± 0.19, shoes 0.95 ± 0.21 CoP excursion in step (mm): rigid 189 ± 38, stiff 174 ± 43, flexible 181 ± 27, shoes 126 ± 35 Ankle pw generation (W/kg): rigid 0.73, stiff 1.21 ± 0.43, flexible 1.43 ± 0.53, shoes 1.49 ± 0.71 WEC (J/Kg/m): rigid 5.5 ± 1.1, stiff 5.4 ± 1.2, flexible 5.6 ± 1.5, shoes 6.1 ± 1.7

Table 1. *Cont.*

References	Study Design	Population	Mean Age	Diagnosis	Level of Functioning	Usage Period	Comparisons	Outcomes	Results
Meyns P et al., 2020 [67]	RCT crossover AFO-CP trial	15, 11 M, 4 F	10 ± 2 yrs, range 6–14 yrs	SCP	GMFCS: 2 level I, 11 level II, 2 level III	acclimatization period of 4–6 wk for each level of stiffness	Three level of stiffness (flexible, stiff, rigid) vAFO vs. shoes	3DGA: trunk kinematics, STP, gait stability (MoS)	Trunk Rot ROM (°): rigid 18.4 ± 4.9, stiff 15 ± 6.2, flexible 13.4 ± 5.9, shoes 11.9 ± 4.4 Trunk Lat ROM (°): rigid 20.5 ± 7.9, stiff 21.9 ± 8.5, flexible 22.6 ± 7.8, shoes 16.7 ± 6 ML_MoS (m): rigid 0.011 ± 0.019 m vs. 0.016 ± 0.021 sdML_MoS (m): rigid 0.026 ± 0.014 m vs. shoes 0.018 ± 0.011 Pearson's correlation between netEC and Trunk ROM: tilt ROM flexible vAFO 0.68, stiff vAFO 0.69; lateroflexion ROM flexible vAFO 0.78, stiff AFO 0.81, rigid AFO 0.78; sdML_MoS flexible vAFO 0.57, rigid vAFO 0.76
Radtka SA et al., 2005 [68]	RCT crossover	12, 6 M and 6 F	7.5 ± 3.83 yrs, range 4–16 yrs	DCP	GMCFS I/II (10 pt)–III (2 pt)	SAFO (9 pt), HAFO (3 pt) (worn for ≥1 yr) − 2 wk no AFO −1 mo SAFO − 2 wk no AFO − 1 mo HAFO	SAFO and HAFO vs. BF	3DGA: kinematics, kinetics, STP; sEMG (muscle timing in ST)	SL (cm): SAFO 86.78 ± 19.11, HAFO 89.92 ± 19.01, shoes 79.03 ± 18.46 cm) DF at IC (°): SAFO 7.09 ± 5.06, HAFO 5.37 ± 7, shoes −8.14 ± 5.46 DF in MSt (°): SAFO 10.59 ± 4.93, HAFO 11.67 ± 7, shoes 0.69 ± 4.3 DF in TSt (°): SAFO 11.50 ± 4.28, HAFO 16.13 ± 6.17, shoes −1.30 ± 6.59 Peak ankle moment at TSt (Nm/kg): SAFO 0.96 ± 0.2, HAFO 0.94 ± 0.25, shoes 0.69 ± 0.14 Peak ankle pw at TSt (W/kg): SAFO −0.60± 0.24, HAFO −0.87 ± 0.42, shoes −0.26 ± 0.33 Peak ankle pw at pSW (W/kg): SAFO 1.16 ± 0.39, HAFO 1.07 ± 0.46, shoes 1.16 ± 0.39
Wojciechowski EA et al., 2022 [69]	RCT crossover	12 (6 M, 6 F)	11.2 ± 3.6 range 5–16 yrs	CMT	Unsp	Unsp	AFO, 3D printed AFO, BF	3DGA: kinematics, kinetics, STP, AFO's features	Peak PF at pSW (°): AFO −4.3 ± 2.5, 3DprintedAFO −5.1 ± 3.3, shoes −15.6 ± 10.9 DF at IC (°): AFO 0 ± 3.5, 3DprintedAFO −0.6 ± 3.7, shoes −5.9 ± 7.6 Peak DF moment in LR (Nm/kg): AFO −0.3 ± 0.1, 3DprintedAFO −0.3 ± 0.1, shoes −0.1 ± 0.1 Peak PF moment in ST (Nm/kg): AFO 1.1 ± 0.3, 3DprintedAFO 1.1 ± 0.3, shoes 0.9 ± 0.3 ↓ weight (−35.2%), ↓ material (−24.4%) vs. traditional AFO

Table 1. *Cont.*

References	Study Design	Population	Mean Age	Diagnosis	Level of Functioning	Usage Period	Comparisons	Outcomes	Results
Wren T et al., 2015 [70]	RCT crossover	10 (6 M, 4 F)	4–12	5 HCP, 5 DCP	GMFCS: I-III	4 wk	DAFO, ADRAFO, BF	3DGA: kinematics, kinetics, STP; OPUS, PODCI, WA	SL (m): BF 0.69 ± 0.21, DAFO 0.79 ± 0.23, ADRAFO 0.85 ± 0.2 HE ST (°): BF 7.6 ± 10.4, DAFO 5 ±9.9, ADRAFO 3.8 ±11 DF ST (°): BF −4.3 ± 11.4, DAFO 8.9 ±4.4, ADRAFO −0.4 ±8.5 DF Sw (°): BF −11.4 ± 11.5, DAFO 5.5 ±4.9, ADRAFO −4.2 ±7.2 KE ST (°): BF 10.9 ± 9.7, DAFO 12.5 ±12.1, ADRAFO 7.1 ±13.7 Peak ankle pw at pSW (W/kg): BF −1.36 ± 0.74, DAFO 0.74 ±.36, ADRAFO 1.06 ± 0.5 WA (steps/day): DAFO 5952, ADRAFO 5224

Legend—3DGA: 3D gait analysis; AFO: ankle foot orthoses; ADRAFO: adjustable dynamic response AFO; BF: barefoot; BOTMP: Bruininks-Oseretsky Test of Motor Proficiency; Cad: cadence; Ca.M.O: carbon modular orthosis; d: day/days; DAFO: dynamic ankle foot orthosis; DF: dorsiflexion, (+) value denotes dorsiflexion, (−) value denotes plantar flexion; DCP: diplegic cerebral palsy; DS: double support; FL: flexion; GMFM: gross motor functional measure; HAFO: hinged ankle-foot orthosis; HCP: hemiplegic cerebral palsy; HF: hip flexion; HE: hip extension; IC: initial contact; ISw: initial swing; KF: knee flexion; KE: knee extension; LR: loading response; ML_MoS: medio-lateral margin of stability; Mo: month; MSt: mid stance; MSw: mid swing; netEC: net energy cost; OPUS: Orthotics and ProstheticsUsers' Survey; PEDI: Pediatric Evaluation of Disability Inventory; PF: plantarflexion; PLS: Posterior leaf spring; PODCI: Pediatric Outcomes Data Collection Instrument; PROM: passive range of motion; PSw: pre-swing; Pw: power; pt: patient/patients; SAFO: solid (or fixed) ankle-foot orthosis; SDCP: spastic diplegic cp; sdML_MoS: standard deviation medio-lateral margin of stability; sl: step length; SL: stride length; SMO: sopra malleolar orthoses; ST: stance phase; STP spatio-temporal parameters; SW: stride width; Sw: swing phase; TA: tibialis anterior; TSt: terminal stance; TSw: terminal swing; Unsp: unspecified; vAFO: ventral shell spring-hinged AFO; WA: walking activity; WEC: walking energy cost; wk: week/weeks; ws: walking speed; yrs: years; M: Male; F: Female; ↓: decrease.

3.3. Meta-Analysis Results

Five RCTs involving children with CP were included in the meta-analysis [63–66,68]. To compare the results, we decided to group solid (SAFO) or fixed AFO [63–65,68] and rigid ventral shell AFO (vAFO) [66] as rigid AFO. Similarly, the following different types of orthoses were clustered as flexible AFO, because they all left flexibility at the ankle: HAFO [63,64,68], stiff and flexible vAFO [66], SMO [65], and PLS [63,64]. The results of the meta-analysis are represented in Figures 4–10.

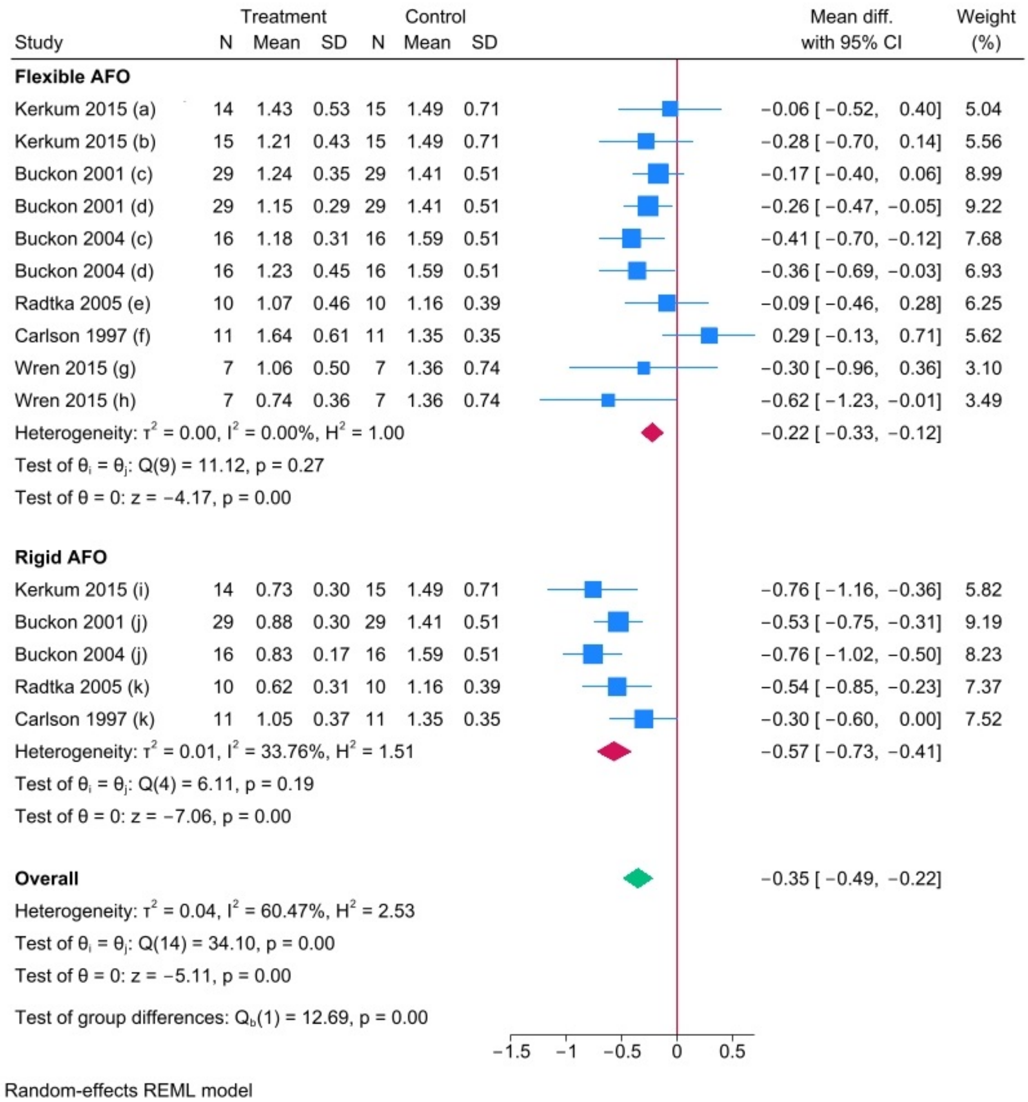

Figure 4. Forest plot showing the meta-analysis of the effectiveness of rigid ankle–foot orthoses (Rigid AFOs) and flexible ankle–foot orthoses (Flexible AFOs) vs. barefoot/shoes on the peak ankle power in pre-swing in children with cerebral palsy. The outcomes are expressed as mean differences (Mean Diff.) in W/Kg. Comparisons: (a) Flexible vAFO vs. shoes; (b) Stiff vAFO vs. shoes; (c) HAFO vs. barefoot; (d) PLS vs. barefoot; (e) HAFO vs. shoes; (f) SMO vs. shoes; (g) ADR-AFO vs. barefoot; (h) DAFO vs. barefoot; (i) Rigid vAFO vs. shoes; (j) SAFO vs. barefoot; (k) SAFO vs. shoes. In blue, effect estimate and associated 95% confidence interval from each included study. In red, pooled estimate from studies included in each subgroup. In green, overall pooled estimate from all included studies [33,63–65,68,70].

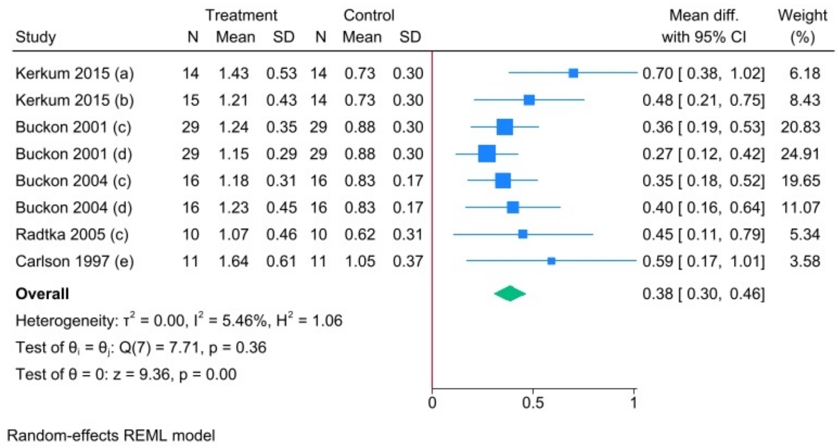

Figure 5. Forest plot showing the meta-analysis of the effectiveness of flexible ankle–foot orthoses (Flexible AFOs) vs. rigid ankle–foot orthoses (Rigid AFOs) on the peak ankle power in pre swing in children with cerebral palsy. The outcomes are expressed as mean differences (Mean Diff.) in W/Kg. Comparisons: (a) Flexible vAFO vs. rigid vAFO; (b) Stiff vAFO vs. rigid vAFO; (c) HAFO vs. SAFO; (d) PLS vs. SAFO; (e) SMO vs. SAFO. In blue, effect estimate and associated 95% confidence interval from each included study. In green, overall pooled estimate from all included studies [33,63–65,68].

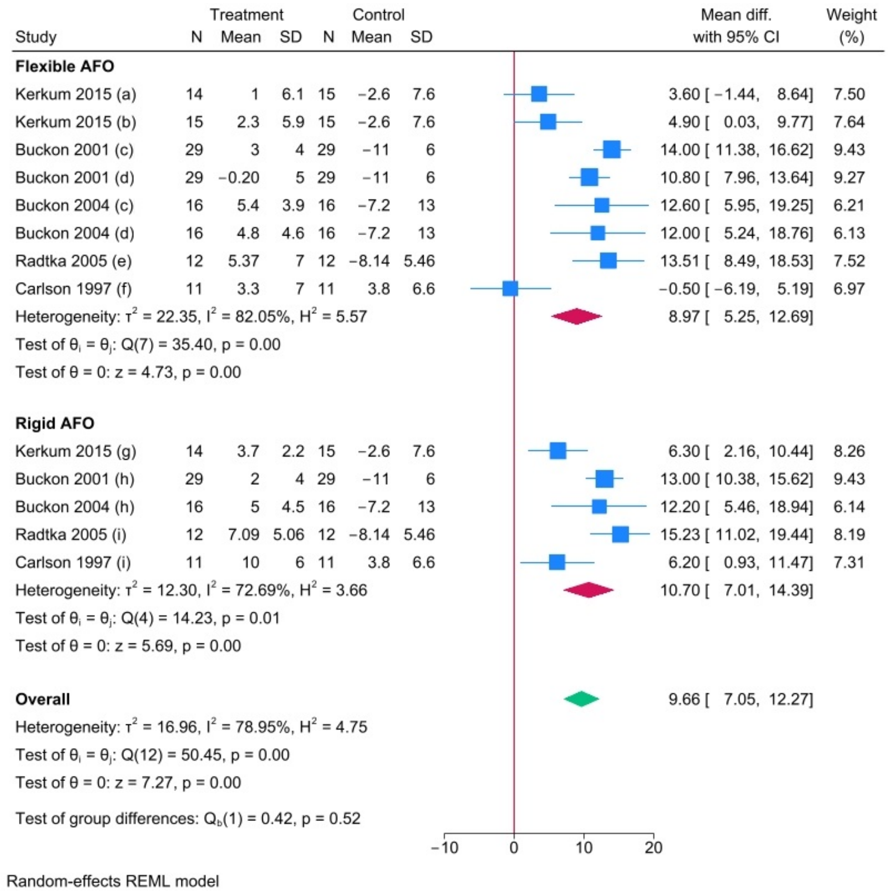

Figure 6. Forest plot showing the meta-analysis of the effectiveness of rigid ankle–foot orthoses (Rigid AFOs) and flexible ankle–foot orthoses (Flexible AFOs) vs. barefoot/shoes on the dorsiflexion at initial contact in children with cerebral palsy. The outcomes are expressed as mean differences (Mean Diff.) in degrees. Comparisons: (a) Flexible vAFO vs. shoes; (b) Stiff vAFO vs. shoes; (c) HAFO vs. barefoot; (d) PLS vs. barefoot; (e) HAFO vs. shoes; (f) SMO vs. shoes; (g) Rigid vAFO vs. shoes; (h) SAFO vs. barefoot; (i) SAFO vs. shoes. In blue, effect estimate and associated 95% confidence interval from each included study. In red, pooled estimate from studies included in each subgroup. In green, overall pooled estimate from all included studies [33,63–65,68].

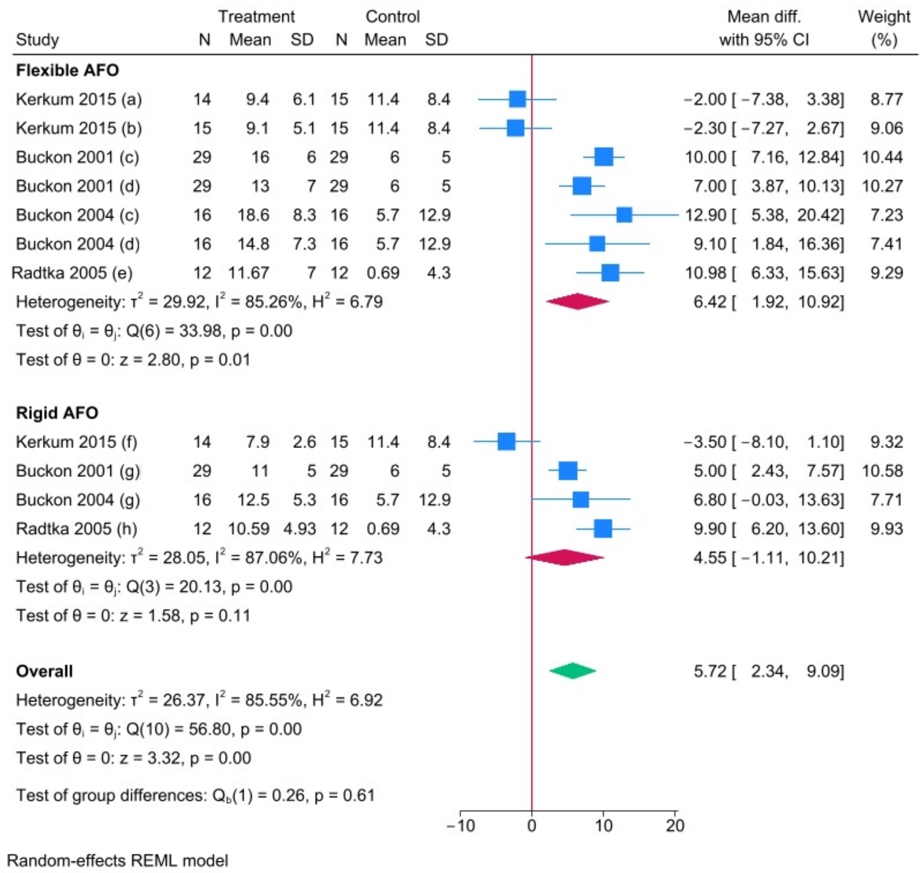

Figure 7. Forest plot showing the meta-analysis of the effectiveness of rigid ankle–foot orthoses (Rigid AFOs) and flexible ankle–foot orthoses (Flexible AFOs) vs. barefoot/shoes on the peak dorsiflexion in stance in children with cerebral palsy. The outcomes are expressed as mean differences (Mean Diff.) in degrees. Comparisons: (a) Flexible vAFO vs. shoes; (b) Stiff vAFO vs. shoes; (c) HAFO vs. barefoot; (d) PLS vs. barefoot; (e) HAFO vs. shoes; (f) Rigid vAFO shoes; (g) SAFO vs. barefoot; (h) SAFO vs. shoes. In blue, effect estimate and associated 95% confidence interval from each included study. In red, pooled estimate from studies included in each subgroup. In green, overall pooled estimate from all included studies [33,63,64,68].

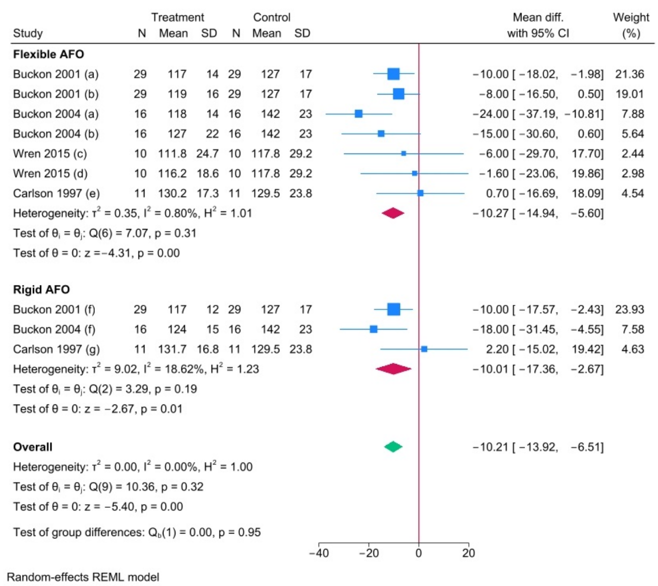

Figure 8. Forest plot showing the meta-analysis of the effectiveness of rigid ankle–foot orthoses (Rigid AFOs) and flexible ankle–foot orthoses (Flexible AFOs) vs. barefoot/shoes on cadence in children with

cerebral palsy. The outcomes are expressed as mean differences (Mean Diff.) in steps per minute. Comparisons: (a) HAFO vs. barefoot; (b) PLS vs. barefoot; (c) DAFO vs. barefoot; (d) ADR-AFO vs. barefoot; (e) SMO vs. shoes; (f) SAFO vs. barefoot; (g) SAFO vs. shoes. In blue, effect estimate and associated 95% confidence interval from each included study. In red, pooled estimate from studies included in each subgroup. In green, overall pooled estimate from all included studies [63–65,70].

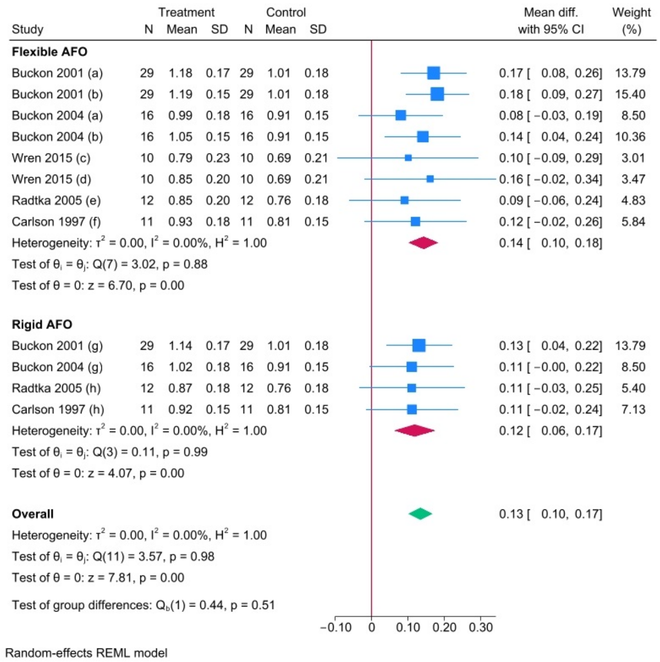

Figure 9. Forest plot showing the meta-analysis of the effectiveness of rigid ankle–foot orthoses (Rigid AFOs) and flexible ankle–foot orthoses (Flexible AFOs) vs. barefoot/shoes on stride length in children with cerebral palsy. The outcomes are expressed as mean differences (Mean Diff.) in meters. Comparisons: (a) HAFO vs. barefoot; (b) PLS vs. barefoot; (c) DAFO vs. barefoot; (d) ADR-AFO vs. barefoot; (e) HAFO vs. shoes; (f) SMO vs. shoes; (g) SAFO vs. barefoot; (h) SAFO vs. shoes. In blue, effect estimate and associated 95% confidence interval from each included study. In red, pooled estimate from studies included in each subgroup. In green, overall pooled estimate from all included studies [63–65,68,70].

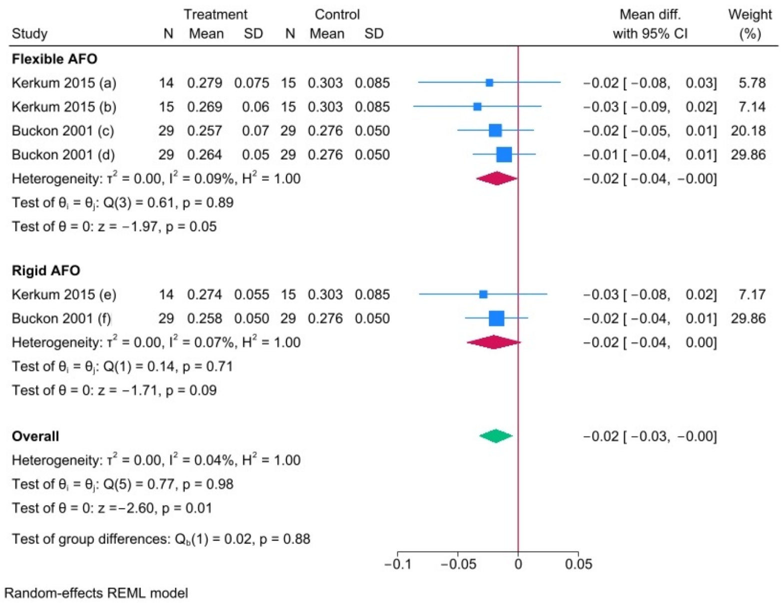

Figure 10. Forest plot showing the meta-analysis of the effectiveness of rigid ankle–foot orthoses (Rigid AFOs) and flexible ankle–foot orthoses (Flexible AFOs) vs. barefoot/shoes on energy cost at

self-selected speed in children with cerebral palsy. The outcomes are expressed as mean differences (Mean Diff.) in mL O_2/Kg/meter. Comparisons: (a) Flexible vAFO vs. shoes; (b) Stiff vAFO vs. shoes; (c) HAFO vs. barefoot; (d) PLS vs. barefoot; (e) Rigid vAFO vs. shoes; (f) SAFO vs. barefoot. In blue, effect estimate and associated 95% confidence interval from each included study. In red, pooled estimate from studies included in each subgroup. In green, overall pooled estimate from all included studies [33,63].

3.4. Undesirable Effects

No undesirable effects were reported except in the study by Kerkum et al. (2015b) [66], in which the authors declared that one child refused to wear the rigid vAFO, and another child could not acclimatize to the flexible vAFO because of pressure marks.

4. Discussion

Interesting data emerged from the meta-analysis of studies involving patients with CP. In general, solid or flexible AFOs reduce the peak ankle power in pre-swing compared to walking barefoot or with only shoes. Nonetheless, the results are heterogeneous, mainly due to findings from flexible AFOs, which are closer to those for controls. This is linked to the reduction in the range of motion (ROM) at the ankle: the ROM is the most limited in rigid AFO, and the moment and power are the lowest at the ankle. The ankle push-off contributes to leg swing and to center of mass acceleration [71]; thus, ankle power should be preserved to improve gait efficiency. Interestingly, the peak ankle power tends to increase compared to control when using SMO [65], which does not limit the ankle sagittal ROM but impedes excessive valgus-pronation, optimizing the action of plantar flexors at push-off. Comparing flexible versus rigid AFO, a significant overall effectiveness regarding peak ankle power in pre swing is confirmed, and results are homogeneous. Based on this, flexible AFOs might be preferable to rigid ones.

On the contrary, excessive flexibility might reduce the effectiveness in promoting dorsiflexion at initial contact. As shown in Figure 6, an overall positive result was achieved considering all types of AFO compared to barefoot or shoes, but the heterogeneity was high mainly due to SMO and flexible vAFO. Dorsiflexion at initial contact allows for "landing" on the heel, as in a typical gait, and precedes reaching plantar support in the stance. Furthermore, it promotes a higher step and stride length.

The meta-analysis demonstrated a significant increase in stride length and a reduction in cadence when comparing all types of AFO versus barefoot/shoes, with no overall heterogeneity. These parameters indicate a more efficient gait.

As a confirmation, an overall reduction in energy cost was demonstrated while walking with AFO at self-selected speed compared to barefoot/shoes. The heterogeneity was almost null. This outcome was measured for a 31 m [63,64] or 6 min walk [66]. Over longer distances, the advantage might be amplified and reduce fatigue; therefore, AFO might promote mobility in ecological contexts.

An overall significant increase in peak ankle dorsiflexion (DF) was observed when comparing AFO versus barefoot/shoes (Figure 7). The results were heterogeneous, mainly due to the study by Kerkum et al. [66]. This might be due to the population included in the study, which presented excessive knee flexion (at least 10°) in the midstance phase. One objective of the proposed AFOs was counteracting excessive knee flexion, therefore reducing ankle dorsiflexion in stance. In general, a proper ankle DF ROM allows for the anterior roll of the tibia relative to the foot during the midstance phase of gait, which contributes to forward movement of the body. A limitation of peak ankle DF affects ground reaction forces and the torque of the lower extremity joints; it reduces the ankle plantar flexor moment and may induce foot external rotation as compensation to allow progression of the tibia [72]. Based on the results of a study on adult normal gait, if the peak ankle dorsiflexion angle is less than 9.03°, the lower limb movement pattern changes significantly [73]. On the contrary, when ankle dorsiflexion in stance is persistent and/or excessive, as the plantar flexors cannot decelerate the progression of the tibia, the ground reaction force is posterior to the knee, creating a flexion moment on the knee, leading to progressively inefficient crouch gait [74].

Non-randomized controlled studies (Supplementary Table S2), involving subjects with CP, substantially confirmed the results of the meta-analysis. The methodological limitations (Figure 3) of these studies do not permit us to draw reliable conclusions on other aspects. Nonetheless, interesting findings are reported regarding the effect of AFOs on trunk displacement [42,56], which is increased on either the transverse or the frontal plane. Similar changes are reported in typically developing children wearing orthoses that limit the ankle ROM [75]. This must be taken into account when considering the introduction of AFOs in subjects with CP, particularly in the presence of trunk asymmetry such as scoliosis.

Walking performance may be conditioned by several factors such as body mass index (BMI); spasticity; recent surgery; concurrent physiotherapy or medications (particularly those to treat spasticity); and the use of assistive devices such as crutches, canes, or a walker. The patient's weight and height are usually considered in computed gait analysis and in the individually customized AFOs, but only two studies have declared it [66,67]. None systematically explored the role of BMI while comparing walking with or without AFOs. Only Ratdka et al. [68] measured spasticity using the Ashworth Scale. Most of the studies explicitly excluded recent surgery [62–64,66–68], but two studies [65,70] did not specify it. Only Borghi et al. [62] reported recent botulinum injections among the exclusion criteria. No one reported whether the patients underwent physiotherapy. Additionally, the studies compared gait without and with orthoses during the same assessment session or after a short accommodation period (usually 4–6 weeks). Therefore, major changes due to BMI or clinical modifications were not believed to have influenced the comparison. All the included subjects were community ambulators, mostly at levels I and II of GMFCS. A few patients at GMFCS level III used assistive devices during the assessment [68,70]. In the studies by Kerkum et al. [66] and Meyns et al. [67], they were included only if they were able to walk independently for at least 15 m, and to perform the gait analysis without external supports.

The limited evidence regarding neuromuscular diseases (CMT and DMD) suggests that, as in CP, AFOs are effective in reducing equinus in swing and improving DF at initial contact, but reduce ankle power generation at pre-swing, unless there is individual adaptation to preserve AFOs' flexibility. Limiting the ankle ROM is critical in patients who incur progressive weakness and usually develop compensatory movements at the trunk.

Limitations

The present systematic review focused on gait performance as the outcome. Many reports were found regarding the effectiveness of AFOs on the gait performance of subjects with CP. Nonetheless, as clinicians, we outline the need for more specific indications to guide the choice of AFO. The studies tended to select samples based on the diagnosis, hemiplegic and/or diplegic CP, but these may include different patterns of gait. Furthermore, several types of AFOs are described as having specific characteristics. The choice to categorize them as flexible or rigid AFOs was functional in the meta-analysis but is a simplification. The meta-analysis was performed after considering the appropriateness of a cross-over design for trials comparing the effect of different AFOs in children with CP and considering that no carry-over effect or period effect was expected. Given the available data, in this meta-analysis, all the measurements from intervention and control periods were analyzed as if the included studies were randomized parallel trials. It should be considered that this approach may have introduced a unit-of-analysis error with the possible consequence of masking clinical heterogeneity, even if this analysis was deemed conservative, according to the Cochrane handbook [76]. As Degelaen [77] affirmed, there are several difficulties "in comparing the evidence related to two distinct orthoses that target different problems in different children". Future studies should focus on specific gait pattern alterations, to compare the effects of different types of AFOs. At the same time, the rebound on other segments (i.e., the trunk) must be considered.

As Morris C. [78] declared, the cross-over design "may overcome the difficulty of the heterogeneity of the cerebral palsies by making each child their own control", but it "does not provide information on the long-term benefits or harm of using different designs of orthoses". Nonetheless, studying the long term effect of AFOs is challenging because of the influence of several factors such as BMI and concurrent treatments (i.e., surgery, spasticity treatment, and physiotherapy). Perhaps innovative multicenter trials involving artificial intelligence will enable the exploration of big data over time and studying the reciprocal relationships between all these factors.

The present study did not consider the children's and adolescents' satisfaction and the effectiveness of AFOs in improving their participation. However, in clinical practice, we experience that the compliance and satisfaction of the "client" mostly influence the use of the orthoses in an ecological context. As Kane et al. [79] recommend based on a recent focus group involving clinicians in Canada to improve AFO prescription, future research should "develop valid and reliable measures of gait quality and participation specific to orthotic evaluation" and "examine parent and child perceptions of AFO intervention in order to understand what is meaningful to clients, and identify the most effective targets for evaluation".

5. Conclusions

The present meta-analysis demonstrates the effectiveness of AFOs in increasing stride length, ankle dorsiflexion at IC, and peak ankle DF in stance, as well as reducing cadence and the energy cost of walking, in children and adolescents with CP. Flexible AFOs are preferable because they preserve the peak ankle power generated at push-off compared to rigid AFOs. The evidence regarding DMD and CMT is limited but suggests opting for flexible AFOs, which partially preserve ankle power generation and, thus, plantar flexors' activity. Nonetheless, further studies should select samples based on specific pathological patterns rather than on the diagnosis, to compare the effects of different types of AFOs and draw more specific indications. Furthermore, the compliance and satisfaction of the users should be considered as outcomes, to include the effectiveness at the participation level of ICF.

Supplementary Materials: The following supporting information can be downloaded at https://www.mdpi.com/article/10.3390/prosthesis7010013/s1: Table S1: Search procedures. Table S2: Characteristics of included non-randomized studies.

Author Contributions: Conceptualization, S.F. and S.P.; methodology, S.F. and F.V.; formal analysis, S.F., E.V., E.P., F.M., G.C., G.T., A.E., A.G. and F.V.; investigation, S.F., E.V., E.P., F.M., G.C., G.T. and A.E.; data curation, S.F.; writing—original draft preparation, S.F. and F.V.; writing—review and editing, S.F., E.V., E.P., F.M., G.C., G.T., A.E., A.G., F.V., S.P. and S.S.; supervision, S.S.; project administration, S.F. All authors have read and agreed to the published version of the manuscript.

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