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Effects of 3D-printed ankle-foot orthoses on gait: a systematic review

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ABSTRACT

This systematic review aimed to explore comprehensive evidence on the efficacy of the 3D-printed ankle-foot orthoses (AFOs) on gait parameters in individuals with neuromuscular and/or musculoskeletal ankle impairments. Electronic databases including PubMed, Scopus, Web of Science, Embase, ProQuest, Cochrane, and EBSCOhost were searched from inception to August 2023. Ten studies that had participants with ankle impairments, as a result of stroke, cerebral palsy, mechanical trauma, muscle weakness, or Charcot-Marie-Tooth disease, investigated the immediate effects of the 3D-printed AFOs on gait parameters were included. Methodological rigor was evaluated using the modified Downs & Black index. The gait parameters included lower extremity joint angles, moments, and work/power, plantar pressures, spatiotemporal measures, and patient satisfaction were improved with the 3D-printed AFOs when compared to the no-AFO (i.e. barefoot, or shoe-only) conditions. 3D-printed AFOs revealed similar functional efficacy as conventional AFOs. Notably, the level of patient satisfaction regarding fitting and comfort was higher with the 3D-printed AFOs. Although the study on the effects of the 3D-printed AFOs are limited, emerging evidence indicates their effectiveness in improving gait biomechanics and functions. To further confirm their effects, rigorous randomized control studies with larger sample sizes and longer follow-ups on the effects are warranted in the future.

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KEYWORDS
Additive manufacturing; AFO; ambulation; biomechanics; lower extremity

Introduction

Individuals with various neuromuscular and/or musculoskeletal ankle disorders, such as weakness of dorsiflexors, motor control deficiencies, spasticity, and/or foot drops, often experience foot and ankle instability during daily activities (Błażkiewicz & Wit, 2019; Figueiredo et al., 2008; Gutierrez et al., 2009; Labanca et al., 2021; Perry & Burnfield, 2010; Singer et al., 2014; Suttmiller & McCann, 2020). Ankle-foot orthoses (AFOs) are often prescribed for individuals with impaired ankles to improve gait stability and performance, and increase independence, comfort, and quality of life (Chisholm & Perry, 2012; Daryabor et al., 2022; Kobayashi et al., 2016, 2017; Totah et al., 2019; Xu et al., 2019). As a conservative treatment, AFOs play an important role in rehabilitative and therapeutic practice. An AFO is a specially designed brace that assists with foot clearance during the swing phase and stabilizes the ankle during the stance phase in ambulation (Alam et al., 2014; Webster & Murphy, 2017). Functionally, there are two main types of AFOs: non-articulated (i.e., solid-ankle, rigid, leaf spring), and articulated (i.e., hinge) AFOs. In practice, clinicians also need to consider several additional design aspects, including trim lines and appropriate materials to achieve the appropriate functional outcomes (Totah et al., 2019).

Recent advancements in additive manufacturing technology (i.e., 3D printing, a computer-aided fabrication technology) and process have shown great potential for customization of orthoses and prostheses (Fu et al., 2022; Wojciechowski et al., 2019). The 3D-printed AFOs may offer numerous advantages, including the ability to create complex structures and intricate designs that optimize weight, stiffness, and energy dissipation, enhance gait performance, and ensure fit and comfort over the conventional AFOs fabricated with plaster bandage casting and molding procedure (Meng et al., 2021; Wojciechowski et al., 2019, 2022). 3D printing offers greater freedom in material selection for various foot regions and enables the design of intricate hollow structures to reduce weight and material wastage, which is challenging in the fabrication process of the conventional AFOs. The conventional mass-produced AFOs often lack the customizability and precision to achieve optimal fit, support, and function for specific patients. Although conventional plaster and fiberglass cast can help to achieve optimal fit of the AFOs, this would not be suitable for complex designs and modifications. On the contrary, the 3D-printed AFOs can be individually tailored based on patient's unique anatomical, pathological, and biomechanical characteristics. The technique of 3D scanning is commonly employed to directly capture the anatomical features of patients' limbs. This personalized approach enhances fit and alignment with greater design freedom and higher fabrication efficiency, resulting in improved

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accessibility, perceived function, and customer satisfaction (Otepbergenov et al., 2020; Schlégl et al., 2022). Specifically, 3D printing technique can significantly reduce lead time and related costs of fabrication compared to conventional plaster casting techniques (Wojciechowski et al., 2019). As all modeling and design manufacturing processes are conducted digitally with minimal guidance, there is no need for laborious plaster casting. Therefore, 3D printing technologies are environment friendly (Garg et al., 2018; Górski et al., 2021).

Recent systematic reviews indicated the high feasibility and practicality of using 3D printing technology to fabricate conventional AFOs, develop intricate AFO designs, and optimize fit, weight, and stiffness (Gupta et al., 2023; Wojciechowski et al., 2019). Although the effectiveness of 3D-printed lower limb orthoses such as foot orthoses or shoe inserts on comfort, physical functioning, cost, and gait biomechanics have been comprehensively investigated in recent reviews (Daryabor et al., 2023; Rodrigues et al., 2021), review of the 3D-printed AFOs are very limited. For example, one systematic review on the mechanical feasibility of the 3D-printed AFOs reported biomechanical functions related to spatiotemporal parameters as well as patient satisfaction and comfort (Wojciechowski et al., 2019). However, it should be noted that the majority of the studies included in this review only included a single participant for the evaluation of gait parameters. Hence, the outcomes may not be generalizable to other settings or populations due to a lack of reproducibility and reliability. To the best of our knowledge, no systematic review has synthesized the effects of the 3D-printed AFOs on gait biomechanics and functions. Despite the growing body of literature on the benefits and advantages of the 3D-printed AFOs, there lacks consensus on their effects on gait parameters. Thus, the aim of this review was to systematically evaluate the literature regarding the influence of 3D-printed AFOs on gait. Specifically, this review addressed the following research questions: (1) Can customized 3D-printed AFOs affect and/or improve gait functions regarding kinematic, kinetic, spatiotemporal parameters, and satisfaction in individuals with ankle impairments? (2) Are there any differences in effectiveness between the traditionally fabricated customized AFOs and the 3D-printed AFOs? The current review of the effects of 3D-printed AFOs on complete gait parameters could help identify gaps in the literature and provide insights for future research.

Methodology

Study protocol

The search strategy was conducted based on the population intervention comparison outcome (PICO) method and subsequent selection was performed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Page et al., 2021). The protocol for this review was registered in PROSPERO (ID: CRD42023441136).

Data sources and search strategy

The search was carried out in electronic databases including PubMed, Scopus, Web of Science, Embase, ProQuest, Cochrane, and EBSCOhost from inception to August 2023. Two sets of keywords (Keyword-1: 3D printing and its synonyms, and Keyword-2: AFO and its synonyms) were selected as search syntax. The relevant search terms were integrated with Boolean operators (i.e., AND, OR, NOR) to develop the search strategy for PubMed, and then other databases were adopted. Two authors (TP and YH) independently evaluated the titles, abstracts, and full texts identified by database searches. Any disputes regarding the screening and selection process were resolved through discussion with the third author (AJ).

Study selection criteria

The acceptability of the identified articles was assessed according to the inclusion criteria as follows: Population: studies that were carried out on participants diagnosed with either neuromuscular or musculoskeletal disorders prescribed to use AFOs; Intervention: studies that investigated 3D-printed or additively manufactured mechanical (passive) AFOs; Comparison: studies that compared the 3D-printed AFOs with the traditionally customized or prefabricated AFOs, barefoot, or shoes; Outcome: clinical trials (including paired samples, non-RCTs, RCTs with parallel or crossover designs) and observational studies with gait variables. Abstract-only, single-case, and non-English studies, as well as studies investigating orthoses other than ankle-foot orthoses were excluded.

Methodological rigor

The methodological rigor of the included studies was evaluated by two independent authors (TP and FM) using the modified Downs and Black checklist (Downs & Black, 1998). The Downs and Black index included 20 items based on modified sections on reporting, external validity, internal validity-bias, internal validity-confounding, and power. Each of the included studies was assessed against these 20 items from the checklist and received "yes" (1 point), "no" (0 point) or "unable to determine" (0 point). A third author (AJ) was consulted to resolve any discrepancies.

Data extraction

Data extraction was performed based on the main characteristics of the studies, including author name with publication year, study design, participants' characteristics (gender, age, ankle-foot status), study comparisons (control and experimental condition), walking pattern (speed and surface), AFO type, shell material, 3D printing technique, and outcome measures. Two independent authors (TP and YH) conducted data extraction to mitigate bias and enhance the accuracy of the data extraction table, and another author (AJ) checked for accuracy and missing or inconsistent data.

Results

Study selection

The literature retrieval process used electronic databases to obtain 3754 potentially relevant articles. After removing duplicates, carefully screening titles and abstracts, 35 articles were deemed eligible for full-text analysis. A total of 25 articles were further excluded during the full-text screening process, and 10 articles that met the eligibility criteria were included in this systematic review. As shown in Figure 1, the article identification and screening process was tracked utilizing the PRISMA method. The articles excluded during full-text analysis were reported with reasons in supplementary Table S2.

Risk of methodological bias

The risk of methodological rigor of each included article regarding reporting, external validity, internal validity bias, internal selection bias, and a priori power estimation was evaluated using the modified Downs and Black quality index (Table 1). Methodological quality was rated at a scientific rigor of 14 out of 20 (median or fair), ranging from 12 (lowest) to 15 (highest). The degree of fulfillment of the criteria for each article varied between 60% and 75%. The worst scores were obtained for the following items: 11 and 12 (participants asked and prepared to participate were representatives of the source population), 14 and 15 (participants blinded to treatment and outcome assessment), 24 (treatment allocation concealed from investigators and participants), and 27 (power estimation used for sample size calculation).

Study characteristics

Comprehensive information regarding the study design, participant demographics, and intervention delivered are presented in Table 2. Ten quasi-experimental studies incorporating 104 participants were considered for the systematic review. Eight of these studies (Creylman et al., 2013; Fu et al., 2022; Harper et al.,

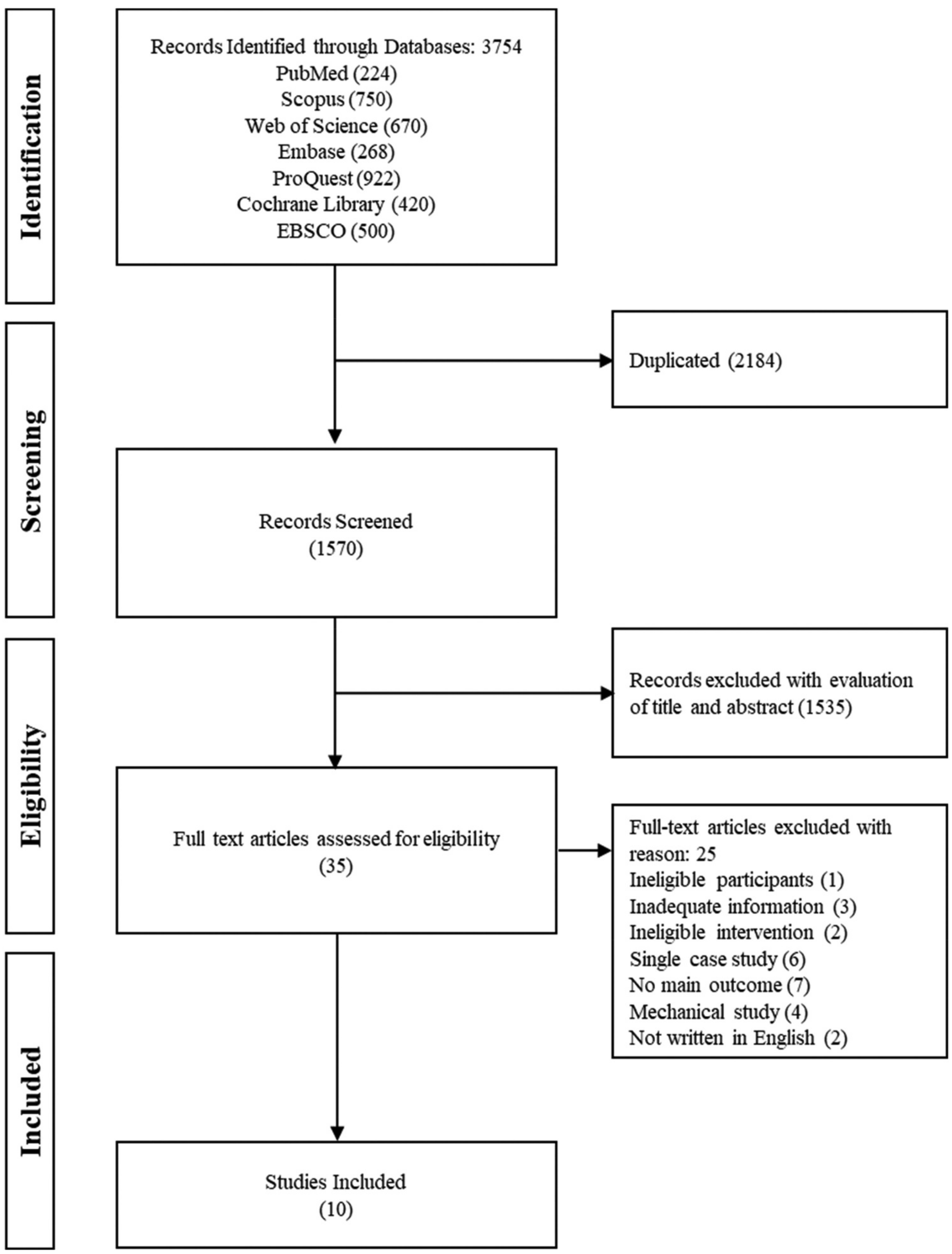

Figure 1. Flowchart indicating the article selection.

Table 1. Modified Downs and Black checklist for methodological rigor.

	Reporting								External validity		Internal validity – bias					Internal validity – Confounding/selection bias				Power	Total score	
Studies	1	2	3	4	5	6	7	10	11	12	14	15	16	18	20	21	22	23	24	27	Out of 20	Quality status
Creylman et al. (2013)	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	0	0	0	13	Fair
Harper et al. (2014b)	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	0	0	14	Fair
Harper et al. (2014a)	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	0	0	14	Fair
Ranz et al. (2016)	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	0	0	14	Fair
Z. Liu, Zhang, Yan, Ren, et al. (2019)	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	0	0	0	13	Fair
Z. Liu, Zhang, Yan, Xie, et al. (2019)	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	0	0	0	13	Fair
Vasiliauskaite et al. (2021)	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	0	0	0	12	Fair
Lin et al. (2021)	1	1	1	1	1	1	1	0	0	0	0	0	1	1	1	1	1	0	0	0	12	Fair
Fu et al. (2022)	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	0	1	15	Good
Wojciechowski et al. (2022)	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	0	0	14	Fair

Note. 1: yes; 0: no and unable to determine or not applicable. 01. Hypothesis/aim/objective clearly described; 02. Main outcomes in Introduction or Methods; 03. Participants characteristics clearly described; 04. Interventions of interest clearly described; 05. Principal confounders clearly described; 06. Main findings clearly described; 07. Estimates of random variability provided for main outcomes; 10. Probability values reported for main outcomes; 11. Subjects asked to participate were representative of source population. (recruited); 12. Subjects prepared to participate were representative of source population. (excluded?); 14. Study participants blinded to treatment.; 15. Blinded outcome assessment; 16. Any data dredging clearly described; 18. Appropriate statistical tests performed; 20. Outcome measures were reliable and valid; 21. All participants in different intervention group recruited from the same source population; 22. All participants in different intervention group recruited over the same time period; 23. Participants randomized to treatment(s); 24. Allocation of treatment concealed from investigators and participants; 27. Statistical power estimation used for sample size calculation.

2014a, 2014b; Lin et al., 2021; Z. Liu, Zhang, Yan, Ren, et al., 2019; Z. Liu, Zhang, Yan, Xie, et al., 2019; Ranz et al., 2016) involved participants with unilateral ankle impairments, one study (Wojciechowski et al., 2022) involved participants with bilateral impairments, and one study (Vasiliauskaite et al., 2021) involved participants with both unilateral and bilateral impairments. Unilateral or bilateral ankle muscle weakness and/or drop foot disorder, commonly associated with stroke (Creylman et al., 2013; Fu et al., 2022; Lin et al., 2021; Z. Liu, Zhang, Yan, Ren, et al., 2019; Z. Liu, Zhang, Yan, Xie, et al., 2019; Vasiliauskaite et al., 2021), Charcot-Marie-Tooth disease (Vasiliauskaite et al., 2021; Wojciechowski et al., 2022), cerebral palsy (Creylman et al., 2013; Vasiliauskaite et al., 2021), and mechanical trauma (Creylman et al., 2013; Harper et al., 2014a, 2014b; Ranz et al., 2016; Vasiliauskaite et al., 2021) were the most prevalent symptoms among participants from various age groups. All studies delivered 3D-printed AFOs whilst comparing gait functions. Of these, four studies (Creylman et al., 2013; Lin et al., 2021; Vasiliauskaite et al., 2021; Wojciechowski et al., 2022) compared gait function with both the conventional AFO and no-AFO conditions. Two studies (Z. Liu, Zhang, Yan, Ren, et al., 2019; Z. Liu, Zhang, Yan, Xie, et al., 2019) compared only with the no-AFO conditions (i.e., either barefoot or shoe-only condition), while four studies (Fu et al., 2022; Harper et al., 2014a, 2014b; Ranz et al., 2016) compared only with the conventional AFOs. In addition, three of these studies (Harper et al., 2014a; Ranz et al., 2016; Wojciechowski et al., 2022) investigated more than one type of 3D-printed AFOs, varying in design and materials.

Three included studies (Fu et al., 2022; Lin et al., 2021; Wojciechowski et al., 2022) used articulated 3D-printed AFOs, and eight studies (Creylman et al., 2013; Harper et al., 2014a, 2014b; Z. Liu, Zhang, Yan, Ren, et al., 2019; Z. Liu, Zhang, Yan, Xie, et al., 2019; Ranz et al., 2016; Vasiliauskaite et al., 2021; Wojciechowski et al., 2022) used non-articulated 3D-printed AFOs. Among the non-articulated AFOs, four were posterior leaf spring AFOs (Creylman et al., 2013; Z. Liu, Zhang, Yan, Ren, et al., 2019; Z. Liu, Zhang, Yan, Xie, et al., 2019; Wojciechowski et al., 2022), four were posterior strut AFOs (Harper et al., 2014a, 2014b; Ranz et al., 2016; Vasiliauskaite et al., 2021), and one was a posterior solid AFO (Wojciechowski et al., 2022). 3D-printing techniques such as selective laser sintering (Creylman et al., 2013; Harper et al., 2014a, 2014b; Ranz et al., 2016; Vasiliauskaite et al., 2021), stereolithography (Z. Liu, Zhang, Yan, Ren, et al., 2019), fused deposition modeling (Lin et al., 2021; Wojciechowski et al., 2022), fused filament fabrication (Fu et al., 2022), and multi-jet fusion (Z. Liu, Zhang, Yan, Xie, et al., 2019) were employed when the AFOs were being fabricated. Nylon including Nylon 12 (Creylman et al., 2013; Wojciechowski et al., 2022), Nylon 11 (Harper et al., 2014a, 2014b; Ranz et al., 2016), and elastic Nylon (Lin et al., 2021), polyamide (Z. Liu, Zhang, Yan, Xie, et al., 2019; Vasiliauskaite et al., 2021), polylactic acid (Fu et al., 2022; Lin et al., 2021), and Somos® NeXt resin (Z. Liu, Zhang, Yan, Ren, et al., 2019) were used as the printing materials in the included studies.

Gait parameters, including kinematics (Creylman et al., 2013; Harper et al., 2014a, 2014b; Lin et al., 2021; Z. Liu, Zhang, Yan, Xie, et al., 2019; Ranz et al., 2016; Vasiliauskaite et al., 2021; Wojciechowski et al., 2022), kinetics (Choi et al., 2017; Fu et al., 2022; Harper et al., 2014a, 2014b; Lin et al., 2021; Ranz et al., 2016; Vasiliauskaite et al., 2021; Wojciechowski et al., 2022), plantar pressure/force (Fu et al., 2022; Wojciechowski et al., 2022), spatiotemporal data (Creylman et al., 2013; Harper et al., 2014a, 2014b; Lin et al., 2021; Z. Liu, Zhang, Yan, Ren, et al., 2019; Z. Liu, Zhang, Yan, Xie, et al., 2019; Ranz et al., 2016; Vasiliauskaite et al., 2021; Wojciechowski et al., 2022), and patient satisfaction (Fu et al., 2022; Lin et al., 2021; Wojciechowski et al., 2022), were the main outcome measures.

3D-printed AFOs effects

The effects of the 3D-printed AFOs on gait parameters including hip, knee, and ankle kinematics and kinetics, plantar pressure distribution, spatiotemporal, and patient satisfaction, retrieved from the included studies are displayed in Tables 3–5.

Table 2. Study characteristics.

		Participants' Characteristics		Study comparisons			AFO			
Author/Year	Study Design	(M/F/U; age)	Type of patient: Ankle foot status	No-AFO cond.	Experimental cond.	Walking pattern (speed, surface)	Type	Shell material	3D-printing technique	Outcomes measures
Creylman et al. (2013)	Single group quasi-experimental	8/0; 46.6 ± 12.5	Stroke, cerebral palsy, hernia, & mechanical trauma: unilateral with drop foot	Barefoot	a. Conventional AFO, b. 3D-printed AFO	On 21.5 m instrumented walkway, self-selected speed	Conv.: non-articulated (posterior leaf), 3D-printed: non-articulated (posterior leaf)	Conv. AFO: PP, 3D-printed AFO: NL 12	SLS (P760 from EOS GmbH, Materialise NV in Leuven, Belgium)	Kinematics (hip, knee, & ankle), Spatiotemporal
Harper et al. (2014b)	Single group quasi-experimental	10/0; 28.7 ± 6.0	Trauma: Unilateral with muscle weakness	Shoe	a. Shoe +conventional AFO, b. Shoe + 3D-printed AFO	On instrumented walkway. self-selected speed	Conv.: non-articulated (posterior strut), 3D-printed: non-articulated (posterior strut)	Conv. AFO: CF, 3D-printed AFO: NL 11	SLS, Vanguard HiQ/ HS (3D Systems, Inc., Rock Hill, SC)	Kinematics (hip, knee & ankle), Kinetics (hip, knee, & ankle moment & work, GRFs), Spatiotemporal
Harper et al. (2014a)	Single group quasi-experimental	13/0; 29.4 ± 5.8	Trauma: Unilateral with muscle weakness	Shoe	a. Shoe +conventional AFO with nominal SLS strut, b. Shoe + 3D-printed AFO with 20% more stiff SLS strut, c. Shoe + 3D-printed AFO with 20% more compliant SLS strut	On instrumented walkway, self-selected speed	Conv.: non-articulated (posterior strut), 3D-printed: non-articulated (posterior strut)	Conv. PD-AFO: CF, 3D-printed PD-AFO: NL	SLS, PA D80-ST (Advanced Laser Materials, LLC, Temple, TX, USA)	Kinematics (hip, knee & ankle), Kinetics (hip, knee, & ankle moment & work, GRFs), Spatiotemporal
Ranz et al. (2016)	Single group quasi-experimental	13/U; 29.54 ± 6.28	Trauma: Unilateral with muscle weakness	Barefoot	a. 3D-printed AFO with proximal bending axis (high), b. 3D-printed AFO with central bending axis (middle) c. 3D-printed AFO (distal bending axis: low)	On instrumented walkway, self-selected speed	Conv.: non-articulated (posterior strut), 3D-printed: non-articulated (posterior struts)	Conv. AFO: CF, 3D-printed PD-AFO: NL 11	SLS (Vanguards HiQ/ HS Sinterstation, 3D Systems, Inc., Rock Hill, SC, USA)	Kinematics (hip, knee & ankle), Kinetics (hip, knee, & ankle moment & work, GRFs), Spatiotemporal
Z. Liu, Zhang, Yan, Ren, et al. (2019)	single group quasi-experimental	8/4; 55.8 ± 9.2	Stroke: Unilateral (≥level 3) with drop foot	Shoe	Shoe +3D-printed AFO	On 12 m straight line, self-selected speed	3D-printed: non-articulated (posterior leaf)	3D-printed AFO: PA 12	MJF (Jet Fusion 3D 4200, HP, USA)	Kinematics (hip, knee &, ankle), Spatiotemporal
Z. Liu, Zhang, Yan, Xie, et al. (2019)	single group quasi-experimental	4/4; 57.25 ± 9.95	Stroke: unilateral (≥level 3) with drop foot	Shoe	Shoe +3D-printed AFO	On 12 m straight line, self-selected speed	3D-printed: non-articulated (posterior leaf)	3D-printed AFO: Somos NeXt	SLA, (Lite450HD-A, UnionTech, China)	Spatiotemporal

(*Continued*)

Table 2. (Continued).

		Participants' Characteristics		Study comparisons			AFO			
Author/Year	Study Design	(M/F/U; age)	Type of patient: Ankle foot status	No-AFO cond.	Experimental cond.	Walking pattern (speed, surface)	Type	Shell material	3D-printing technique	Outcomes measures
Vasiliauskaite et al. (2021)	Single group quasi-experimental	3/3; 24.8 ± 18.4 (8-56)	CMT, Cerebral palsy, Trauma: unilateral and bilateral (≥level 3) with drop foot	Shoe	a. Shoe +conventional AFO, b. Shoe + 3D-printed AFO	On instrumented walkway, self-selected speed	Conv.: Non-articulated (posterior leaf) 3D-printed: non-articulated (posterior strut)	Conv. AFO: PP, 3D-printed AFO: PA	SLS (N.V, Wetteren, Belgium)	Kinematics (hip, knee & ankle), Kinetics (hip, knee, & ankle moment & work), Spatiotemporal
Lin et al. (2021)	Single group quasi-experimental	3/9; 55.58 ± 5.9	Stroke: Unilateral with drop foot	Shoe	a. Shoe +Conventional AFO, b. Shoe + 3D-printed AFO	On instrumented walkway, self-selected speed	Conv.: non-articulated (anterior leaf), 3D-printed: articulated	Conv. AFO: TP, 3D-printed AFO: PLA, NL elastic, TA	FDM (ATOM 2.5EX 3D printer from Layer One, Taipei, Taiwan)	Kinematics (hip, knee & ankle), Kinetics (knee moment & power), Spatiotemporal, Patient satisfaction
Fu et al. (2022)	Single group quasi-experimental	8/2; 54 ± 13	Stroke: unilateral (level 3-4) with drop foot	Barefoot	a. Conventional AFO, b. 3D-printed AFO	On 10 m instrumented walkway, self-selected speed	Conv.: non-articulated (anterior leaf), 3D-printed: articulated (hinged)	Conv. AFO: TP, 3D-printed AFO: PLA	FFF (MINGDER 3D Printing 500S, Kaohsiung, Taiwan)	Kinetics (plantar pressure, force, contact area), Patient satisfaction
Wojciechowski et al. (2022)	Single group quasi-experimental	6/6; 11.2 ± 3.6	CMT: bilateral with drop foot	Shoe	a. Shoe +conventional AFO, b. Shoe + 3D-printed replica AFO c. Shoe + 3D-printed redesigned AFO	On 8 m instrumented walkway, self-selected speed	Conv.: both articulated (hinged) and non-articulated (posterior leaf, solid), 3D-printed replica: both articulated (hinged) and non-articulated (posterior leaf, solid) 3D-printed redesigned: aperture, flexible or thicker tapered strut, hinged footplate	Conv. AFO: PP, 3D-printed replica AFO: NL 12, 3D-printed redesigned AFO: NL 12	FDM (Fortus 450 mc, Stratasys, MN, USA).	Kinematics (hip, knee & ankle), Kinetics (hip, knee, & ankle moment & power, plantar pressure), Patient satisfaction

Note. AFO: ankle foot orthosis, 3D: three dimensional, CMT: Charcot-Marie-Tooth, cond.: condition, conv.: conventional, SLS: selective laser sintering, SLA: stereolithography, FDM: fused deposition modeling, FFF: fused filament fabrication, MJF: multi-jet fusion, NL: nylon, PA: polyamide, TA: titanium alloy, PLA: polylactic acid, TP: thermoplastic, PP: polypropylene.

Table 3. Main findings (3D-printed AFOs versus barefoot/shoe-only condition).

Gait parameters	Key findings	P value	SMD	Reference
Hip kinematics	3D-printed AFO and convention AFO ↑ hip flexion at heel strike than barefoot condition	$p = .009$, $p = .001$	0.248 [−0.735, 1.23], 0.333 [−0.653, 1.32]	Creylman et al. (2013)
	↔ between 3D-printed AFO (replica and redesigned) and shoe-only conditions in peak hip flexion	$p > .05$	-	Wojciechowski et al. (2022)
Hip kinetics	3D-printed AFO ↑ positive hip work at stance than shoe only condition.	$p < .05$	0.487 [−0.662, 1.635]	Vasiliauskaite et al. (2021)
Knee kinematics	3D-printed-AFO and conventional AFO ↓ knee flexion at heel strike than barefoot condition	$p < .001$, $p = .001$	0.532 [−1.52, 0.465], 0.266 [−1.25, 0.718]	Creylman et al. (2013)
	3D-printed-AFO ↓ knee flexion at swing phase than barefoot condition	$p = .005$, $p = .361$	0.160 [−1.14, 0.821], 0.000 [−0.979, 0.979]	Creylman et al. (2013)
	↔ between 3D-printed AFO (replica and redesigned) and shoe-only conditions in knee flexion at heel strike	$p > .05$	-	Wojciechowski et al. (2022)
	↔ between 3D-printed AFO (replica and redesigned) and shoe-only conditions in peak knee flexion at stance	$p > .05$	-	Wojciechowski et al. (2022)
	↔ between 3D-printed AFO (replica and redesigned) and shoe-only conditions in knee flexion at swing	$p > .05$	-	Wojciechowski et al. (2022)
	3D-printed AFO and conventional AFO ↓ peak knee extension at stance than shoe-only condition	$p < .05$	−0.707 [−1.87, 0.46], −0.492 [−1.64, 0.66]	Vasiliauskaite et al. (2021)
Knee kinetics	3D-printed-AFO ↑ knee flexor moment at 35-60% of stance than barefoot condition	$p < .05$	-	Lin et al. (2021)
	3D-printed-AFO ↑ positive knee power at 40-60% stance than barefoot condition	$p < .05$	-	Lin et al. (2021)
	↔ between 3D-printed AFO (replica and redesigned) and shoe-only conditions in peak knee flexor moment at single stance	$p > .05$	-	Wojciechowski et al. (2022)
Ankle kinematics	3D-printed-AFO and conventional AFO ↓ ankle plantarflexion at heel strike than barefoot condition	$p < .001$	1.744 [−2.89, −0.592], 1.715 [−2.86, −0.568]	Creylman et al. (2013)
	3D-printed-AFO and conventional AFO ↓ ankle plantarflexion at swing than barefoot condition	$p < .001$	2.12 [−3.34, −0.895]	Creylman et al. (2013)
	3D-printed AFO and conventional AFO ↓ ankle plantarflexion at heel strike than shoe-only condition	$p < .05$	0.654 [−0.50, 1.82], 0.786 [−0.38, 1.96]	Vasiliauskaite et al. (2021)
	3D-printed replica, 3D-printed redesigned, and conventional AFO ↓ peak ankle plantarflexion at push-off than shoe-only condition	$p < .05$	-	Wojciechowski et al. (2022)
	3D-printed-AFO and conventional AFO ↓ ankle plantarflexion at swing than barefoot condition	$p = .002$, .003	-	Lin et al. (2021)
	3D-printed replica and conventional AFO ↑ ankle dorsiflexion at heel strike than shoe-only condition	$p < .05$	-	Wojciechowski et al. (2022)
	3D-printed-AFO and conventional AFO ↑ ankle dorsiflexion at swing than barefoot condition	$p < .05$	-	Lin et al. (2021)
	3D-printed AFO and conventional AFO ↓ ankle dorsiflexion at stance than shoe-only condition	$p < .001$, .05	−0.571 [−1.72, 0.58], −0.580 [−1.74, 0.58]	Vasiliauskaite et al. (2021)
	↔ between 3D-printed AFO (replica and redesigned) and shoe-only conditions in ankle dorsiflexion at stance	$p > .05$	-	Wojciechowski et al. (2022)
	3D-printed-AFO and conventional AFO ↓ sagittal plane ankle ROM than shoe-only condition	$p < .01$, .05	−1.182 [−2.40, 0.04], −1.161 [−2.38, 0.06]	Vasiliauskaite et al. (2021)
	3D-printed-AFO and conventional AFO ↓ sagittal plane ankle ROM than barefoot condition	$p < .001$	2.29 [−3.51, −1.06], 2.06 [−3.23, −0.884]	Creylman et al. (2013)
Ankle kinetics	3D-printed-AFO ↑ peak ankle plantarflexor moment at 40-60% stance than barefoot condition	$p > .05$	-	Lin et al. (2021)
	3D-printed-AFO ↑ ankle power at 40-60% stance than barefoot condition	p > .05	-	Lin et al. (2021)
	3D-printed replica AFO and conventional AFO ↑ peak ankle plantarflexor moment than shoe-only condition	$p < .001$, $p < .05$	-	Wojciechowski et al. (2022)
	3D-printed replica, redesigned, and conventional AFO ↑ peak ankle dorsiflexor moment than shoe-only condition	$p < .001$, $p < .05$	-	Wojciechowski et al. (2022)
	3D-printed AFO and conventional AFO ↑ peak ankle plantarflexor moment than shoe-only condition	$p > .05$	0.352 [−0.78, 1.49], 0.230 [−0.90, 1.36]	Vasiliauskaite et al. (2021)
	↔ between 3D-printed AFO (replica and redesigned) and shoe-only conditions in ankle power at stance	$p > .05$	-	Wojciechowski et al. (2022)

(*Continued*)

Table 3. (Continued).

Gait parameters	Key findings	P value	SMD	Reference
Plantar pressure/ force	3D-printed replica, redesigned, and conventional AFO ↓ peak plantar pressure at total plantar surface than shoe-only condition	$p < .001$, $p < .05$	-	Wojciechowski et al. (2022)
	3D-printed replica, redesigned, and conventional AFO ↓ peak plantar pressure at forefoot than shoe-only condition	$p < .05$	-	Wojciechowski et al. (2022)
	3D-printed replica, redesigned, and conventional AFO ↓ peak plantar pressure at rearfoot than shoe-only condition	$p < .05$	-	Wojciechowski et al. (2022)
	↔ between 3D-printed AFO (replica and redesigned) and shoe-only conditions in peak plantar pressure at midfoot	$p > .05$	-	Wojciechowski et al. (2022)
	3D-printed-AFO ↑ peak plantar pressure at the medial midfoot than barefoot condition	$p = .01$	1.138 [0.193, 2.08]	Fu et al. (2022)
	3D-printed-AFO and conventional AFO ↑ medial midfoot contact area of the affected limb than barefoot condition	$p = .01$, $p = .04$	0.680 [−0.221, 1.58]	Fu et al. (2022)
	3DP-printed AFO ↓ medial midfoot contact asymmetry index between affected and unaffected leg than conventional AFO and barefoot conditions	$p = .04$	0.859 [−1.77, 5.72]	Fu et al. (2022)
	↔ between 3D-printed AFO (replica and redesigned) and shoe-only conditions in total plantar contact area	$p > .05$	-	Wojciechowski et al. (2022)
Spatiotemporal	3D-printed-AFO and conventional AFO ↑ stride length than barefoot condition	$p < .001$	1.006 [−3.42, 2.04], 1.155 [9.63, 2.21]	Creylman et al. (2013)
	3D-printed-AFO and conventional AFO ↑ stride length than shoe-only condition	$p < .05$	0.706 [−0.46, 1.87], 0.363 [−0.77, 1.50]	Vasiliauskaite et al. (2021)
	3D-printed AFO ↑ stride length than barefoot condition	$p = .002$	0.476 [−0.335, 1.28]	Z. Liu, Zhang, Yan, Ren, et al. (2019)
	3D-printed AFO ↑ stride length than barefoot condition	$p = .021$	0.377 [−0.611, 1.36]	Z. Liu, Zhang, Yan, Xie, et al. (2019)
	3D-printed-AFO ↑ stride length than barefoot condition	$p < .05$	0.005 [−0.805, 0.794]	Lin et al. (2021)
	3D-printed AFO ↑ cadence than barefoot condition	$p = .117$	0.455 [−0.355, 1.26]	Z. Liu, Zhang, Yan, Ren, et al. (2019)
	3D-printed AFO ↑ cadence than barefoot condition	$p = .05$	0.233 [−0.750, 1.21]	Z. Liu, Zhang, Yan, Xie, et al. (2019)
	↔ between 3D-printed AFO and barefoot condition in double limb stance time	$p = .075$	0.500 [−1.31, 0.312]	Z. Liu, Zhang, Yan, Ren, et al. (2019)
	↔ between 3D-printed AFO and barefoot condition in double limb stance time	$p = .133$	0.510 [−1.505, 0.486]	Z. Liu, Zhang, Yan, Xie, et al. (2019)
	↔ between 3D-printed AFO and barefoot condition in stance time and swing time	$p = .143$	0.285 [−1.08, 0.518]	Z. Liu, Zhang, Yan, Ren, et al. (2019)
	↔ between 3D-printed AFO and barefoot condition in stance time and swing time	$p = .066$	0.202 [−1.18, 0.780]	Z. Liu, Zhang, Yan, Xie, et al. (2019)
	3D-printed-AFO ↑ swing time than barefoot condition	$p < .05$	1.812 [−2.76, −0.861]	Lin et al. (2021)
	3D-printed-AFO and conventional AFO ↑ stance time than barefoot condition	$p = .004$	0.543 [−0.454, 1.54], 0.484 [−0.510, 1.47]	Creylman et al. (2013)
	3D-printed AFO and conventional AFO ↑ stance time than shoe-only condition	$p < .05$	0.80 [−0.38, 1.98], 0.481 [−0.67, 1.63]	Vasiliauskaite et al. (2021)
	3D-printed AFO ↑ gait velocity than barefoot condition	$p = .001$	0.460 [−0.350, 1.27]	Z. Liu, Zhang, Yan, Ren, et al. (2019)
	3D-printed AFO ↑ gait velocity than barefoot condition	$p = .021$	0.465 [−0.528, 1.45]	Z. Liu, Zhang, Yan, Xie, et al. (2019)
	3D-printed AFO ↑ gait velocity than shoe-only condition	$p < .01$	0.323 [−0.82, 1.46]	Vasiliauskaite et al. (2021)
	3D-printed-AFO ↑ gait velocity than barefoot condition	$p < .05$	0.008 [−0.808, 0.791]	Lin et al. (2021)

Note. ↑:significantly increased; ↓: significantly decreased; ↔: no significant differences; AFO: ankle foot orthosis; ROM: range of motion; 3D: three dimensional.

Table 4. Main findings (3D-printed AFOs versus conventional AFOs).

Gait parameters	Key findings	P value	SMD	Reference
Hip kinematics	↔ between 3D-printed-AFO and conventional AFO in hip flexion at heel strike	$p = .396$	0.124 [−1.104, 0.856]	Creylman et al. (2013)
	↔ between 3D-printed-AFO and conventional AFO in hip flexion at stance	$p > .05$	–	Harper et al. (2014b)
	↔ between 3D-printed AFO (replica and redesigned) and conventional AFO in peak hip flexion	$p > .05$	–	Wojciechowski et al. (2022)
Hip kinetics	↔ between 3D-printed-AFO and conventional AFO in hip joint moments	$p > .05$	–	Harper et al. (2014b)
	3D-printed-AFO ↑ hip extensor moment at heel strike with the affected limb than conventional AFO condition	$p = .040$	–	Harper et al. (2014b)
	3D-printed-AFO ↑ positive hip work at midstance with the affected limb than conventional AFO condition	$p = .046$	–	Harper et al. (2014b)
Knee kinematics	↔ between 3D-printed AFO and conventional AFO in knee flexion at heel strike	$p < .001$	−0.106 [−1.24, 1.03]	Vasiliauskaite et al. (2021)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in knee flexion at heel strike	$p > .05$	–	Wojciechowski et al. (2022)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in knee flexion at stance	$p > .05$	–	Wojciechowski et al. (2022)
	↔ between 3D-printed-AFO and conventional AFO in knee flexion at stance	$p > .05$	–	Harper et al. (2014b)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in knee flexion at swing	$p > .05$	–	Wojciechowski et al. (2022)
	3D-printed-AFO ↓ knee flexion at heel strike than conventional AFO	$p < .001$	0.286 [−1.27, 0.699]	Creylman et al. (2013)
	3D-printed-AFO ↓ knee flexion at swing phase than conventional AFO	$p = .001$	0.153 [−1.134, 0.828]	Creylman et al. (2013)
Knee kinetics	↔ between 3D-printed-AFO and conventional AFO in knee flexor moment at stance	$p > .05$	–	Harper et al. (2014b)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in peak knee flexor moment at single stance	$p > .05$	–	Wojciechowski et al. (2022)
	↔ between 3D-printed AFO and conventional AFO in knee work at stance	$p > .05$	0.060 [−1.07, 1.20]	Vasiliauskaite et al. (2021)
	↔ between 3D-printed-AFO and conventional AFO in knee work at stance	$p > .05$	–	Harper et al. (2014b)
Ankle kinematics	↔ between 3D-printed-AFO and conventional AFO in peak ankle plantarflexion at heel strike	$p = .608$	0 [−0.979, 0.979]	Creylman et al. (2013)
	↔ between 3D-printed-AFO and conventional AFO in peak ankle plantarflexion at swing	$p = .355$	0 [−0.979, 0.979]	Creylman et al. (2013)
	↔ between 3D-printed replica AFO and conventional AFO in peak ankle plantarflexion at push-off	$p > .05$	–	Wojciechowski et al. (2022)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in ankle dorsiflexion at stance	$p > .05$	–	Wojciechowski et al. (2022)
	3D-printed-AFO ↓ peak ankle plantarflexion at heel strike with affected limb than conventional AFO condition	$p = .025$	–	Harper et al. (2014b)
	3D-printed-AFO ↓ peak ankle plantarflexion at early swing with affected limb than conventional AFO condition	$p = .004$	–	Harper et al. (2014b)
	3D-printed replica and 3D-printed redesigned AFO ↓ peak ankle plantarflexion at push-off than conventional AFO	$p < .05$	–	Wojciechowski et al. (2022)
	3D-printed AFO ↓ peak ankle plantarflexion at push-off than conventional AFO	$p < .05$	–	Wojciechowski et al. (2022)
	3D-printed redesigned AFO ↑ ankle dorsiflexion at heel strike than conventional AFO	$p < .05$	–	Wojciechowski et al. (2022)
	3D-printed redesigned AFO ↑ ankle dorsiflexion at swing than conventional AFO	$p < .05$	–	Wojciechowski et al. (2022)
	3D-printed-AFO ↓ ankle dorsiflexion at 40-60% stance with affected limb than conventional AFO condition	$p = .017$	–	Harper et al. (2014b)
	↔ between 3D-printed-AFO and conventional AFO in sagittal plane ankle ROM	$p > .05$		Vasiliauskaite et al. (2021)
	3D-printed-AFO ↓ sagittal plane ankle ROM than conventional AFO condition	$p < .001$	0.4 [−1.38, 0.589]	Creylman et al. (2013)
Ankle kinetics	↔ between 3D-printed-AFO and conventional AFO in ankle moments at stance	$p > .05$	–	Harper et al. (2014b)
	↔ between 3D-printed-AFO and conventional AFO in ankle work at stance	$p > .05$	–	Harper et al. (2014b)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in ankle power at stance	$p > .05$	–	Wojciechowski et al. (2022)
	3D-printed redesigned AFO ↑ peak ankle dorsiflexor moment than conventional AFO condition	$p < .05$	–	Wojciechowski et al. (2022)
Plantar pressure/force	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in peak plantar pressure at rearfoot	$p > .05$	–	Wojciechowski et al. (2022)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in peak plantar pressure at midfoot	$p > .05$	–	Wojciechowski et al. (2022)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in peak plantar pressure at forefoot	$p > .05$	–	Wojciechowski et al. (2022)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in total plantar contact area	$p > .05$	–	Wojciechowski et al. (2022)
Spatiotemporal				
	↔ between 3D-printed-AFO and conventional AFO in stride length	$p = .629$	0.045 [−1.02, 0.935]	Creylman et al. (2013)
	↔ between 3D-printed-AFO and conventional AFO in stride length	$p > .05$	–	Harper et al. (2014b)
	↔ between 3D-printed-AFO and conventional AFO in cadence	$p > .05$	0.153 [−0.98, 1.28]	Vasiliauskaite et al. (2021)
	↔ between 3D-printed-AFO and conventional AFO in cadence	$p = .60$	0.295 [−1.17, 0.586]	Fu et al. (2022)
	↔ between 3D-printed-AFO and conventional AFO in stance time	$p = .993$	0.000 [−0.979, 0.979]	Creylman et al. (2013)
	↔ between 3D-printed-AFO and conventional AFO in stance time	$p > .05$	–	Harper et al. (2014b)
	↔ between 3D-printed-AFO and conventional AFO in swing time	$p > .05$	–	Harper et al. (2014b)
	↔ between 3D-printed-AFO and conventional AFO in step width	$p > .05$	–	Harper et al. (2014b)
	↔ between 3D-printed-AFO and conventional AFO in gait velocity	$p = .97$	0.000 [−0.876, 0.876]	Fu et al. (2022)

(*Continued*)

Table 4. (Continued).

Gait parameters	Key findings	P value	SMD	Reference
Patient satisfaction	↔ between 3D-printed-AFO and conventional AFO in satisfaction regarding dimension	$p = .53$	–	Fu et al. (2022)
	3D-printed-AFO ↑ satisfaction regarding dimension than conventional AFO condition	$p < .001$	1.955 [0.982, 2.92]	Lin et al. (2021)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in fitting	$p > .05$	–	Wojciechowski et al. (2022)
	↔ between 3D-printed-AFO and conventional AFO in "ease in adjusting the parts"	$p = .31$	–	Fu et al. (2022)
	↔ between 3D-printed-AFO and conventional AFO in "ease in adjusting the parts"	$p > .05$	–	Lin et al. (2021)
	↔ between 3D-printed-AFO and conventional AFO in "easy-to-use"	$p = .08$	–	Fu et al. (2022)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in "easy-to-use"	$p > .05$	–	Wojciechowski et al. (2022)
	3D-printed AFO ↑ satisfaction regarding easy-to-use than conventional AFO	$p < .05$	0.406 [−0.402, 1.21]	Lin et al. (2021)
	↔ between 3D-printed-AFO and conventional AFO in weight	$p = .06$	–	Fu et al. (2022)
	↔ between 3D-printed-AFO and conventional AFO in weight	$p > .05$	–	Lin et al. (2021)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in weight	$p > .05$	–	Wojciechowski et al. (2022)
	↔ between 3D-printed AFO and conventional AFO in "effective to needs"	$p = .24$	–	Fu et al. (2022)
	3D-printed AFO ↑ satisfaction regarding "effective to needs" than conventional AFO	$p < .001$	1.859 [0.901, 2.81]	Lin et al. (2021)
	↔ between 3D-printed AFO and conventional AFO in comfort	$p = .67$	–	Fu et al. (2022)
	↔ between 3D-printed AFOs (replica and redesigned) and conventional AFO in comfort	$p > .05$	–	Wojciechowski et al. (2022)
	3D-printed AFO ↑ satisfaction regarding comfort than conventional AFO	$p < .001$	1.342 [0.456, 2.22]	Lin et al. (2021)

Note. ↑: significantly increased; ↓: significantly decreased; ↔: no significant differences; AFO: ankle foot orthosis; ROM: range of motion; 3D: three dimensional.

Comparison between 3D-printed AFOs and no AFO

The systematic review identified several notable effects of the 3D-printed AFOs on hip, knee, and ankle mechanics compared to the no-AFO condition (Table 3). Hip flexion at heel strike was found to be increased with the 3D-printed AFOs (Creylman et al., 2013). Additionally, positive hip work at stance with the affected limb was higher when using the 3D-printed AFOs (Vasiliauskaite et al., 2021). In terms of knee mechanics, knee flexion at heel strike and during the swing phase was reduced with the 3D-printed AFOs in one study (Creylman et al., 2013), while no significant changes reported in another study (Wojciechowski et al., 2022). However, peak knee extension during stance phase was decreased with the 3D-printed AFOs (Vasiliauskaite et al., 2021). The knee flexor moment between 35% and 60% of the stance phase was increased with the 3D-printed AFOs, as was positive knee power during the 40% to 60% stance phase (Lin et al., 2021). However, no significant differences were observed in knee flexor moment at single stance when comparing the 3D-printed AFOs to the no-AFO condition (Wojciechowski et al., 2022). In terms of ankle mechanics, ankle plantarflexion was reduced at heel strike, push-off, and during the swing phase when using the 3D-printed AFOs, including various design modifications (Creylman et al., 2013; Harper et al., 2014b; Lin et al., 2021; Vasiliauskaite et al., 2021; Wojciechowski et al., 2022). Ankle dorsiflexion at heel strike and during the swing phase was increased with the 3D-printed AFOs (Vasiliauskaite et al., 2021; Wojciechowski et al., 2022). Ankle dorsiflexion at stance decreased in one study (Vasiliauskaite et al., 2021) while no significant changes in another (Wojciechowski et al., 2022). The sagittal plane ankle ROM was also found to be reduced with the 3D-printed AFOs compared to the no-AFO condition (Creylman et al., 2013; Vasiliauskaite et al., 2021). The peak plantarflexor moment during stance phase was higher with the 3D-printed AFOs (Lin et al., 2021; Vasiliauskaite et al., 2021; Wojciechowski et al., 2022). Consequently, the ankle power/force exerted at the stance phase was increased in one study when using the 3D-printed AFOs (Lin et al., 2021).

The systematic review also highlighted several notable effects of the 3D-printed AFOs on plantar pressure and spatiotemporal parameters when compared to the no-AFO condition (Table 3). Peak plantar pressure under the rearfoot, forefoot, and total plantar surface was reduced with the 3D-printed AFOs (Fu et al., 2022; Wojciechowski et al., 2022). Peak plantar pressure under the midfoot was increased in one study (Fu et al., 2022) while reported no significant changes in the other study (Wojciechowski et al., 2022). The medial midfoot contact area of the affected limb increased, leading to a decrease in the asymmetry index between the affected and non-affected limbs (Fu et al., 2022). Stride length was found to be longer with the 3D-printed AFOs (Creylman et al., 2013; Lin et al., 2021; Z. Liu, Zhang, Yan, Ren, et al., 2019; Z. Liu, Zhang, Yan, Xie, et al., 2019; Vasiliauskaite et al., 2021). Stance time was also longer with the 3D-printed AFOs (Creylman et al., 2013; Vasiliauskaite et al., 2021). Furthermore, cadence (steps per minute) increased when using the 3D-printed AFOs (Z. Liu, Zhang, Yan, Ren, et al., 2019; Z. Liu, Zhang, Yan, Xie,

Table 5. Main findings (3D-printed AFO with the variations in bending stiffness).

Gait parameters	Key findings	P value	SMD	Reference
Hip kinematics				
	↔ across nominal, 20% more compliant, and 20% more stiff struts in hip flexion	$p > .05$	–	Harper et al. (2014a)
	↔ across bending axis positions (proximal, central, and distal) in hip flexion	$p > .05$	–	Ranz et al. (2016)
			–	
Hip kinetics	↔ among nominal SLS strut, 20% more stiff SLS strut and 20% more compliant SLS strut in hip joint moments	$p > .05$	–	Harper et al. (2014a)
	↔ among nominal SLS strut, 20% more stiff SLS strut and 20% more compliant SLS strut in hip joint work	$p > .05$	–	Harper et al. (2014a)
	↔ across nominal, 20% more compliant, and 20% more stiff struts in hip joint moments	$p > .05$	–	Harper et al. (2014a)
	↔ across bending axis positions (proximal, central, and distal) in hip joint moments	$p > .05$	–	Ranz et al. (2016)
			–	
Knee kinematics	3D-printed-AFO with both nominal and 20% stiff struts ↑ peak knee flexion than 20% compliant strut.	$p < .05$	-	Harper et al. (2014a)
	↔ across bending axis conditions (proximal, central, and distal) in peak knee angles	$p > .05$	–	Ranz et al. (2016)
			–	
Knee kinetics	3D-printed-AFO with 20% stiff struts ↑ negative knee joint work than 20% compliant strut	$p < .05$	–	Harper et al. (2014a)
	↔ across nominal, 20% compliant, and 20% stiff struts in knee joint moments	$p > .05$	–	Harper et al. (2014a)
	↔ across bending axis positions (proximal, central, and distal) in knee joint moments	$p > .05$	–	Ranz et al. (2016)
			-	
Ankle kinematics	3D-printed AFO with 20% stiff strut ↓ plantarflexion than both nominal and 20% compliant struts.	$p < .05$	–	Harper et al. (2014a)
	3D-printed AFO with proximal bending axis ↓ plantarflexion than central bending axis.	$p < .05$	–	Ranz et al. (2016)
	3D-printed AFO with 20% stiff strut ↓ dorsiflexion than both nominal and 20% compliant struts.	$p < .05$	–	Harper et al. (2014a)
	3D-printed AFO with proximal bending axis ↓ dorsiflexion than central bending axis.	$p < .05$	–	Ranz et al. (2016)
Ankle kinetics			–	
	↔ among nominal SLS strut, 20% more stiff SLS strut and 20% more compliant SLS strut in ankle joint moments	$p > .05$	–	Harper et al. (2014a)
	↔ among nominal SLS strut, 20% more stiff SLS strut and 20% more compliant SLS strut in ankle joint work	$p > .05$	–	Harper et al. (2014a)
	↔ across nominal, 20% compliant, and 20% stiff struts in ankle joint moments	$p > .05$	–	Harper et al. (2014a)
	↔ across bending axis positions (proximal, central, and distal) in ankle joint moments	$p > .05$	–	Ranz et al. (2016)
			–	
Plantar pressure/force	3D-printed-AFO with 20% stiff struts ↑ medial GRF impulses than 20% compliant strut	$p < .05$	–	Harper et al. (2014a)
	3D-printed-AFO with central bending ↑ vertical GRF impulses than both proximal and distal bending axis	$p < .05$	–	Ranz et al. (2016)

Note. ↑:significantly increased; ↓: significantly decreased; ↔: no significant differences; AFO: ankle foot orthosis; ROM: range of motion; 3D: three dimensional.

et al., 2019; Vasiliauskaite et al., 2021). Consequently, gait velocity increased with the use of 3D-printed AFOs (Lin et al., 2021; Z. Liu, Zhang, Yan, Ren, et al., 2019; Z. Liu, Zhang, Yan, Xie, et al., 2019; Vasiliauskaite et al., 2021).

Comparison between 3D-printed AFOs and conventional AFOs

The systematic review revealed several key findings regarding the use of the 3D-printed AFOs compared to the conventional AFOs (Table 4). The areas of hip and knee mechanics with no notable differences included peak hip flexion, hip flexion at heel strike and mid-stance (Creylman et al., 2013; Harper et al., 2014b; Wojciechowski et al., 2022), hip joint moments (Harper et al., 2014b), knee flexion at heel strike, stance, and during the swing phase (Harper et al., 2014b; Vasiliauskaite et al., 2021; Wojciechowski et al., 2022), knee flexor moments during stance (Harper et al., 2014b; Wojciechowski et al., 2022), and knee power/work during stance (Harper et al., 2014b; Vasiliauskaite et al., 2021). However, hip extensor moment and positive hip work at mid-stance with the affected limb were increased with the 3D-printed AFOs in one study (Harper et al., 2014b). Additionally, one study reported reduced knee flexion at heel strike and during the swing phase (Creylman et al., 2013). There were no significant differences in ankle plantarflexion at heel strike, stance, push-off, and during the swing phase in two studies (Creylman et al., 2013; Wojciechowski et al., 2022), while ankle plantarflexion at push-off and early swing was reduced with the 3D-printed AFOs in two studies (Harper et al., 2014b; Wojciechowski et al., 2022). Ankle dorsiflexion increased at heel strike and during the swing phase with the 3D-printed AFOs featuring design modification in one study (Wojciechowski et al., 2022), while it decreased during the stance phase in another study (Harper et al., 2014b). Additionally, one study reported an increase in ankle dorsiflexor moment with the modified 3D-printed AFOs compared to the conventional AFOs (Wojciechowski et al., 2022).

Other gait parameters with no significant differences included sagittal plane ankle ROM (Vasiliauskaite et al., 2021), plantarflexor moment (Harper et al., 2014b; Wojciechowski et al., 2022), ankle joint work/power (Harper et al., 2014b; Wojciechowski et al., 2022), peak plantar pressure at rearfoot, midfoot, and forefoot (Wojciechowski et al., 2022), total plantar contact area (Wojciechowski et al., 2022), stride length (Creylman et al., 2013; Harper et al., 2014b), cadence (Fu et al., 2022), double limb stance time, stance time, swing time (Creylman et al., 2013; Harper et al., 2014b; Z. Liu, Zhang, Yan, Ren, et al., 2019; Z. Liu, Zhang, Yan, Xie, et al., 2019), and gait velocity (Fu et al., 2022). One study (Lin et al., 2021) reported increased satisfaction with the dimensions and fitting of the 3D-printed ankle-foot orthoses (AFOs) compared to the conventional AFOs. While two other studies (Fu et al., 2022; Wojciechowski et al., 2022) found no significant differences. Regarding "easy-to-use" and "effective to needs," one study (Lin et al., 2021) observed higher satisfaction with the 3D-printed AFOs, while another study (Fu et al., 2022) found no significant differences. Comfort levels were reported to be higher with the 3D-printed AFOs in one study (Lin et al., 2021), whereas two studies (Fu et al., 2022; Wojciechowski et al., 2022) did not find significant differences. No significant differences in patient satisfaction were noted between the 3D-printed and conventional AFOs in terms of "ease in adjusting parts" (Fu et al., 2022; Lin et al., 2021), fitting (Wojciechowski et al., 2022), and the weight of the AFOs (Fu et al., 2022; Lin et al., 2021; Wojciechowski et al., 2022).

Comparison among 3D-printed AFOs with variations in design and material

Effects of the 3D-printed AFOs with the variations in strut stiffness as well as the position of bending axis were compared in two studies (Harper et al., 2014a; Ranz et al., 2016) (Table 5). Plantarflexion and dorsiflexion were decreased with 20% more stiff strut when compared to the nominal as well as 20% more compliant struts. Peak knee flexion was increased with the nominal as well as 20% more stiff struts when compared to 20% more compliant strut. A negative knee joint work as well as the medial GRF impulses were increased with the 20% more stiff strut when compared to 20% more compliant struts (Harper et al., 2014a). However, there were no significant differences in joint moments as well as hip flexion angles when compared among nominal, 20% more compliant, and 20% more stiff struts conditions. Additionally, the effects of the 3D-printed AFOs with the variations in the position of the bending axis (no bending, central bending, proximal bending, and distal bending axis) were compared in one included study (Ranz et al., 2016). Plantarflexion and dorsiflexion were decreased with proximal bending axis when compared to central bending axis. The trend of increased peak knee flexion was observed with proximal bending axis when compared to central bending as well as distal bending axis. The vertical GRF impulses were increased with the central bending when compared to either proximal or distal bending axis (Ranz et al., 2016). However, there were no significant differences in lower limb joint moments as well as hip flexion angles when compared among different bending axis positions.

Discussion

This review aimed to systematically collect and evaluate the current state of the evidence for the effectiveness of the 3D-printed AFOs in terms of gait biomechanics and performance in individuals with ankle impairments. This review summarized research investigating gait parameters with the 3D-printed AFOs. Of the 10 included studies, nine studies were rated as fair and one as good in methodological quality. All studies showed typical methodological flaws including small and heterogeneous samples, lack of controlled designs, randomization, blinding, and follow-up. Furthermore, heterogeneity in study design and outcome measures made it difficult to pool multiple data under each outcome for further comparison. Nevertheless, the present review highlighted consistent changes in gait parameters with the 3D-printed AFOs compared with the no-AFO condition. The changes in lower extremity kinematics, kinetics, and spatiotemporal parameters were similar to the traditionally fabricated conventional AFOs with comparable effectiveness, while the 3D-printed AFOs showed increased patient satisfaction.

3D-printed AFOs versus barefoot/shoe-only condition

The main purposes of the AFOs are to limit excessive plantarflexion at swing to obtain sufficient toe clearance, to effectively position the foot during heel strike and to provide maximum external stability for the hip-knee-ankle-foot complex in all three planes of motion (Lusardi et al., 2019). The effectiveness of the AFOs in controlling functions of lower extremity kinematics and kinetics for individuals with ankle impairments has been well documented (Daryabor et al., 2018; Tyson et al., 2013). With the 3D-printed AFOs, plantarflexion and knee flexion were decreased at heel strike, push-off and swing phase, this may indicate that the AFO effectively restricts foot drop and aids in foot clearance during the swing phase. When the ankle joint was not in dorsiflexion, additional knee flexion is no longer required to facilitate the clearance. While hip flexion at heel strike increased when compared to the no-AFO condition, this may demonstrate that wearing the AFO enhances stability, enabling the hip joint to attain a greater degree of flexion during gait. The peak plantar flexor and knee flexor moments and subsequent positive hip, knee, and ankle power/work were also increased with both the 3D-printed and conventional AFOs when compared to the no-AFO condition. These results are in line with the previous studies that reported greater positive work and lower energy cost of locomotion with an appropriate AFO than that of locomotion with the no-AFO condition in individuals with ankle impairment (Buckon et al., 2004; Franceschini et al., 2003; Lusardi et al., 2019).

The customization of AFOs using the 3D-printing techniques increased the plantar contact area of the affected limb, improved plantar pressure redistribution when compared with the no-AFO condition (Fu et al., 2022). The 3D printed and conventional customizations of the AFOs showed similar changes in plantar contact area and pressure distribution to custom foot orthoses (Khodaei et al., 2017; Wojciechowski et al., 2022; Xu et al., 2019). The increase in total contact area with the improved plantar pressure distribution and arch drop could reduce the backward force, which help secure appropriate thrust during the heel rocker of the stance phase and prevent foot slap (Khodaei et al., 2017; Xu et al., 2019). The spatiotemporal parameters including stride length, cadence, stance time, and gait velocity were increased with both the 3D-printed and conventional AFOs than the no-AFO condition and were similar between the two AFO conditions. Studies on spatiotemporal parameters with the conventional AFOs also reported consistent effects on individuals with unilateral drop-foot (Amitrano et al., 2022; Choo & Chang, 2021; Franceschini et al., 2003).

3D-printed AFOs versus conventional AFOs

When comparing the effect of 3D-printed AFOs with the conventional AFOs on hip and knee flexion, there were no significant differences. The differences between the 3D-printed AFOs and the conventional AFOs in plantarflexion and dorsiflexion at push-off and early swing, as well as the ankle dorsiflexor moment might be attributed to the variations in design, materials, and strut stiffness (Harper et al., 2014a, 2014b; Totah et al., 2019; Wojciechowski et al., 2022). For example, carbon fiber strut with energy storage capability was reported beneficial for impaired ankle compared with both the conventional AFOs and shoe-only condition (Danielsson & Sunnerhagen, 2004; Patzkowski et al., 2012). Similar to lower extremity kinematics, there were no differences in hip, knee, and ankle moments and power/work between the 3D-printed and conventional AFO conditions. This suggests that 3D-printed AFOs are as effective as conventional AFOs in terms of gait mechanics when managing the instability of individuals with ankle impairments.

The changes in lower extremity angles, moments, and power/works during heel strike and midstance in the AFOs with customized shape and dynamic ankle flexion system (e.g., leaf spring, hinge) might lead to the improved spatiotemporal parameters. Disruption of natural foot rocker functions (heel, ankle, and toe rocker) may negatively affect spatiotemporal parameters during the stance phase of forward progression over the foot (Webster & Murphy, 2017). During the stance phase, the heel and ankle rockers might have been enhanced by the AFOs, thus improving the lower extremity function and subsequent spatiotemporal parameters. During heel rocker, an AFO may assist in controlling the plantarflexion of the foot from the neutral position at heel strike to foot flat. During ankle rocker throughout the midstance, an AFO could provide some external stabilization and assist in the rotation of the tibia from 10 degrees of plantarflexion to dorsiflexion over the talus around the ankle joint (Webster & Murphy, 2017). Thus, the AFOs with customization and dynamic ankle flexion system could help replace some of the eccentric contraction of the impaired quadriceps and tibialis anterior to prevent foot slap during heel strike as well as the gastrocnemius and soleus muscles to control the forward progression of the tibia over the talus around the ankle joint through the midstance (Lusardi et al., 2019; Webster & Murphy, 2017). However, to fulfill appropriate toe rocker function, the AFOs had to assist in converting foot complex from its flexible adaptor function at early stance to rigid lever function at late stance. This will allow body weight to roll over the metatarsophalangeal joint with the help of gastrocnemius-soleus muscle complex. Unfortunately, it was insufficient to demonstrate improvement in toe rocker function since other related parameters such as plantarflexion at push-off, plantarflexor moment, and work at push-off were not improved with either the 3D-printed or conventional AFOs. Future studies should examine the efficacy of the AFOs fabricated with the 3D-printed and conventional techniques on these gait functions.

The level of patient satisfaction regarding dimension and fitting, ease in adjusting the parts and use, weight, and comfort of the AFOs was reported not significantly different between the 3D-printed and conventional conditions. These results revealed that the 3D-printed AFOs were perceived similarly to the conventional AFOs while increasing patient satisfaction compared to the no-AFO condition. A recent study on three individuals with unilateral drop-foot reported positive satisfaction in thinness, lightweight, comfort, and gait adjustability when using the 3D-printed AFOs (Cho et al., 2023). Interestingly, one study reported greater improvements in dimension and fitting, easy to use, and comfort with the 3D-printed AFOs when compared to the conventional AFOs (Lin et al., 2021). This might be attributed to the distinct features of the joints as the 3D-printed AFOs incorporated with the hinge articulated feature, while the conventional AFOs used an anterior leaf spring for ankle flexion. Though most of the previous studies reported positive patient satisfaction with the conventional AFOs when compared to the no-AFO condition (Holtkamp et al., 2015; Jor et al., 2023; Zuccarino et al., 2021), some studies indicated negative or no significant differences (Jor et al., 2023; Zuccarino et al., 2021). This discrepancy might be related to the design (e.g., color, trimline, opening) and geometry (contour, fit) of the AFOs. The 3D-printed customization can help adjust these features and enhance the level of satisfaction. By taking into account the individual deformity, such as deformed bony prominence, joint stiffness, and muscle contracture, the 3D-printed AFOs can effectively mediate pressure concentration on the foot, trim lines and padding to unload sensitive areas, and reduce friction or rubbing at the device skin interface (Zuccarino et al., 2021). Hence, 3D-printed customization could be more effective at correcting foot posture, reducing plantar pressure, and enhancing overall patient satisfaction.

3D-printed AFOs with the variations in bending stiffness

With the advancement of 3D printing technology, AFOs can now be tailored individually to a greater extent to meet specific requirements and fit each user well. However, the design and mechanical properties of the 3D-printed AFOs can have a significant impact on gait biomechanics. Previous studies (Harper et al., 2014a; Ranz et al., 2016) have provided insights into how variations in strut stiffness and the position of the bending axis in the 3D-printed AFOs affect lower limb kinematics and kinetics during walking. The reduction in plantarflexion and dorsiflexion with increased strut stiffness suggests that stiffer struts limit the ROM at the ankle joint, potentially providing greater stability but at the cost of reduced ankle mobility and push-off power. This reduction in ankle mobility could lead to compensatory mechanisms in the gait cycle, for instance increased peak knee flexion, which was observed with both nominal and stiffer struts compared to compliant ones. The increase in negative knee joint work and medial GRF impulses with stiffer struts indicates that the knee may be absorbing more energy, possibly due to a less smooth transition from stance to swing phase caused by the lower push-off power (Bregman et al., 2011; Kobayashi et al., 2011). In addition, a previous systematic review demonstrated bending stiffness in the conventional AFOs could influence kinematics, gait stability, and energy efficiency (Totah et al., 2019).

The reduction in plantarflexion and dorsiflexion with altered bending axis position indicates that the position of the bending axis can also influence the degree of motion allowed at the metatarsophalangeal joint as well as the ankle joint. An increase in peak knee flexion with a proximal bending axis suggests that the knee compensates for the limited ankle motion, similar to the findings on strut stiffness. Despite changes in ankle and knee mechanics, both studies reported no significant differences in joint moments or hip flexion angles across different 3D-printed AFO designs. This could imply that while design variations in the 3D-printed AFOs can alter the function of the ankle and knee, the hip joint is affected to a lesser degree to maintain a consistent movement pattern despite changes in the lower limb.

In the realm of orthotic intervention, the 3D-printed AFOs have emerged as a promising technology that offers customization and potential benefits over traditional fabrication methods. The current review highlighted the importance of patient satisfaction, which is often reported to be higher with the 3D-printed AFOs due to their custom fit and comfort (Silva et al., 2022), this is a prerequisite to facilitate long-term compliance. However, evaluating patient satisfaction presents unique challenges, as it is inherently subjective and could be influenced by individual expectations and experiences. To ensure reliable and valid assessments, future studies should incorporate standardized, validated patient-reported outcome measures that are sensitive to the nuances of orthotic interventions (Balkman et al., 2023). Long-term outcomes are another critical aspect of evaluating the efficacy of the 3D-printed AFOs. While short-term benefits in gait parameters are evident, the durability and sustained impact on quality of life remain uncertain. Traditional AFOs have a well-documented track record of long-term use (Geboers et al., 2002; X. Liu et al., 2018; Nikamp et al., 2019), but the novel materials and production processes of the 3D-printed AFOs necessitate rigorous long-term investigations to ascertain their performance over time. Such investigations should incorporate not only the physical integrity of the AFOs but also the sustainability of gait functions and patient satisfaction over extended periods. Incorporating IMU or step activity devices could be considered to monitor the step activity and gait stability when using the new AFOs (Jor et al., 2023).

Standardized outcome measures are paramount for the advancement of research on the 3D-printed AFOs. The heterogeneity in study design and outcome measures observed in the current systematic review impedes the ability to compare results across studies and synthesize data in meta-analyses. To address this, consensus on a core set of outcome measures that are relevant to gait biomechanics, performance, and patient satisfaction, as well as being reliable, and responsive to changes in orthotic interventions is needed. The methodological flaws were identified in the current body of literature, including small sample sizes and lack of controlled designs, highlighting the need for more rigorous randomized controlled trials (RCTs). Future RCTs should target isolating design features and larger and more diverse populations to enhance generalizability and blinding, and randomization will be included to minimize bias in the analysis (Moher et al., 2010). Additionally, incorporating follow-up assessments could provide valuable data on the long-term efficacy and safety of the 3D-printed AFOs.

Limitation

There are some limitations to this systematic review when interpreting our results. Only a small number of studies with no statistical a priori power calculation were identified to summarize the effectiveness of the 3D-printed AFOs in individuals with ankle impairments. The inclusion criteria appear too broad (e.g., different ages of individuals with neuromuscular and/or musculoskeletal ankle impairments) and it is difficult to extend the overall outcomes to a specific type of impairment. The included studies only reported immediate effects of the 3D-printed AFOs when compared to the control condition without considering the duration of AFO use, which may significantly change the level of patient satisfaction (Rahmani et al., 2022). The variations in interventions of the 3D-printed and conventional AFOs were not only limited to fabrication techniques. Materials, bending stiffness, and ankle flexion system of the AFOs may also influence the gait parameters. Additionally, the study designs of the included studies were mainly randomized and non-randomized quasi-experimental and none was randomized controlled trial. The wide range of intervention designs and outcome measures, as well as limited data for pooling under each outcome measure, precluded a meta-analysis.

Conclusion

Our systematic review suggests that the AFOs with 3D-printed customization are feasible and acceptable for individuals with ankle impairments. The 3D-printed AFOs improved lower extremity kinematics and kinetics, plantar pressure, spatiotemporal parameters, and the level of satisfaction in individuals with ankle impairments, particularly when compared to the no-AFO condition. The effects of the 3D-printed AFOs were similar to those of the conventionally fabricated AFOs. However, it is important to consider the inherent variability in human gait, the difficulty of isolating the effects of AFO design from other contributing factors, limited sample sizes, and the range of AFO bending stiffness tested. Therefore, more rigorous randomized control studies with adequate sample sizes and follow-up periods are recommended to confirm the effectiveness of the 3D-printed AFOs on gait parameters and satisfaction.

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