

REVIEW ARTICLE

CONTENTS

Clinical evaluation of custom-made 3d-printed ankle-foot orthoses: Effectiveness, safety, and clinical implications

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ABSTRACT

Aim: To review clinical evidence regarding the effectiveness, safety, and practical implications of custom-made 3D-printed ankle-foot orthoses in individuals with lower limb impairments.

Materials and Methods: A structured literature review was conducted through PubMed and the MAUDE adverse event database. Studies were included if they investigated custom-made 3D-printed mechanical AFOs and reported outcomes related to clinical effectiveness or safety. A total of 278 records were identified; after two-stage screening, 17 studies met the inclusion criteria.

Conclusions: Custom-made 3D-printed AFOs represent an effective and safe solution for individualized management of lower limb impairments. Evidence from 17 studies demonstrates improvements in gait kinematics, plantar pressure distribution, spatiotemporal parameters, and patient satisfaction, with outcomes equivalent to conventionally manufactured devices. No serious adverse events were identified. Future research should prioritize large-scale randomized controlled trials with standardized outcome measures and longer follow-up periods.

KEY WORDS: ankle-foot orthosis, 3D printing, additive manufacturing

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INTRODUCTION

Individuals with various neuromuscular and musculoskeletal ankle disorders, including weakness of dorsiflexors, motor control deficiencies, spasticity, and foot drop, frequently experience foot and ankle instability during daily activities [1, 2]. Ankle-foot orthoses (AFOs) are among the most commonly prescribed conservative interventions for individuals with lower limb impairments. They are designed to assist with foot clearance during the swing phase of gait and to stabilise the ankle during the stance phase, thereby improving mobility, independence, and quality of life [3, 4].

Traditional custom-made AFOs are typically manufactured from thermoplastic materials using plaster casting and moulding techniques. This process is labour-intensive, requires several hours of hands-on work, and is associated with significant health and safety concerns for orthotists [5]. Furthermore, conventional mass-produced prefabricated AFOs often lack the customisability and anatomical precision required for optimal clinical outcomes [6].

In recent years, additive manufacturing, commonly referred to as 3D printing, has emerged as a transformative technology in orthotics and prosthetics. This approach enables the production of highly individualised devices based on digital scans of the patient's anatomy using computer-aided design (CAD) software, offering significant advantages: reduced fabrication time, lower material waste, greater design freedom, and the ability to create complex structures that optimise weight, stiffness, and energy dissipation [7, 8].

Powers et al. evaluated the reliability and validity of low-cost 3D limb scanning for AFO fitting in 30 healthy participants using the Structure Sensor (Occipital Inc.) with Design Studio software. All Pearson correlation coefficients between physical and scan-based measurements were ≥0.80, and the majority of intraclass correlation coefficients exceeded 0.95. Minimal detectable change values for foot and ankle measures were below 4 mm for intrarater reliability and below 6 mm for circumferential and length measures. The authors concluded that low-cost 3D limb scanning provides valid and reliable measurements of lower limb geometry for the purpose of AFO fitting under clinically standardised conditions [9].

Farhan et al. compared the accuracy and speed of seven commercially available 3D scanners for capturing foot, ankle, and lower leg morphology in 10 healthy participants. The Artec Eva (mean accuracy 2.5%, standard deviation 4.5), Structure Sensor I (-1.1%, standard deviation 6.8), and Structure Sensor Mark II (-1.7%, standard deviation 7.5) were the only devices within the predefined acceptable accuracy threshold of ≤5%. The Structure Sensor I was the fastest scanner (mean 20.8 s), while the Spectra required the longest scanning time (329.6 s). Mobile photogrammetry-based applications (Trnio 11 and Trnio 12) demonstrated the lowest accuracy and are not recommended for AFO fabrication. The authors concluded that the Artec Eva, Structure Sensor I, and Structure Sensor Mark II provide the most accurate and fastest digital acquisition of limb morphology for 3D-printed AFO production [10].

The 3D-printed orthoses are usually custom-made medical devices that are manufactured from different materials such as thermoplastic polyurethane (TPU), polyamide (PA), polypropylene (PP), and polylactic acid (PLA). These materials are selected according to their mechanical properties, including plasticity. Despite the fact that the device is used for a specific patient, modern 3D printers provide the possibility of mass manufacturing. According to the European Medical Device Regulation, custom-made devices of lower classes are not subject to mandatory certification by Notified Bodies [11]. Therefore, it is important to confirm the efficiency and safety of 3D-printed orthoses due to the presence of health risks for the patient associated with their use, especially falls.

AIM

The aim of this review was to synthesize current evidence regarding the clinical effectiveness, safety profile, and practical implications of custom-made 3D-printed AFOs for individuals with lower limb impairments.

MATERIALS AND METHODS

A structured literature review was conducted in accordance with the clinical evaluation requirements of Medical Device Regulation No 2017/745. The search was performed in PubMed and complemented by adverse event searches in the MAUDE database (FDA, USA). The search terms were: "ankle foot orthosis 3D", "AFO 3D", "ankle foot orthosis PA12", and "AFO PA12". The last 2 were used as PA material that complies with ISO 10993 biocompatibility requirements. The updated systematic review by Wang et al. was also consulted to identify additional relevant primary studies [12].

INCLUSION AND EXCLUSION CRITERIA

Studies were included if they: (1) investigated 3D-printed or additively manufactured mechanical AFOs; (2) addressed custom-made orthoses; (3) reported outcomes related to safety and clinical effectiveness; and (4) were published in English. Studies were excluded if they: concerned non-AFO orthoses, investigated serially manufactured (non-custom) devices, used other fabrication methods, or were duplicates identified across searches.

QUALITY ASSESSMENT

The methodological quality of included studies was assessed using criteria defined in MEDDEV 2.7.1 Appendix D, evaluating the appropriateness of device, clinical application, patient population, and reporting quality (R1–R3 scale). The modified Downs and Black checklist was also applied [13].

STUDY SELECTION

The initial database search identified 278 potentially relevant publications. Following title and abstract screening, 254 articles were excluded: different research focus (n=135), other orthosis type (n=34), duplicate results (n=82), retracted article (n=1), not in English (n=1), and not related to orthoses (n=1). Full texts of 24 articles were retrieved and evaluated, resulting in the exclusion of 7 further studies: other orthosis types (n=3), different research focus (n=1), focus on scanning methodology (n=1), unspecified orthosis type (n=1), and absence of clinical results (n=1). A total of 17 studies were included in the final analysis. The literature selection process is presented in Fig. 1.

STUDY CHARACTERISTICS

The 17 included studies covered a broad range of clinical populations, sample sizes, and methodological designs. Sample sizes ranged from 1 to 124 participants. The most represented clinical conditions were post-stroke drop foot (~25%), Charcot-Marie-Tooth disease (CMT), cerebral palsy, plantar fasciitis, and mechanical trauma. Other studies by Xu et al. (n=60, RCT) [14] and Pollen et al. (n=104 across 10 studies, systematic review) [15] also represented significant evidence contributions.

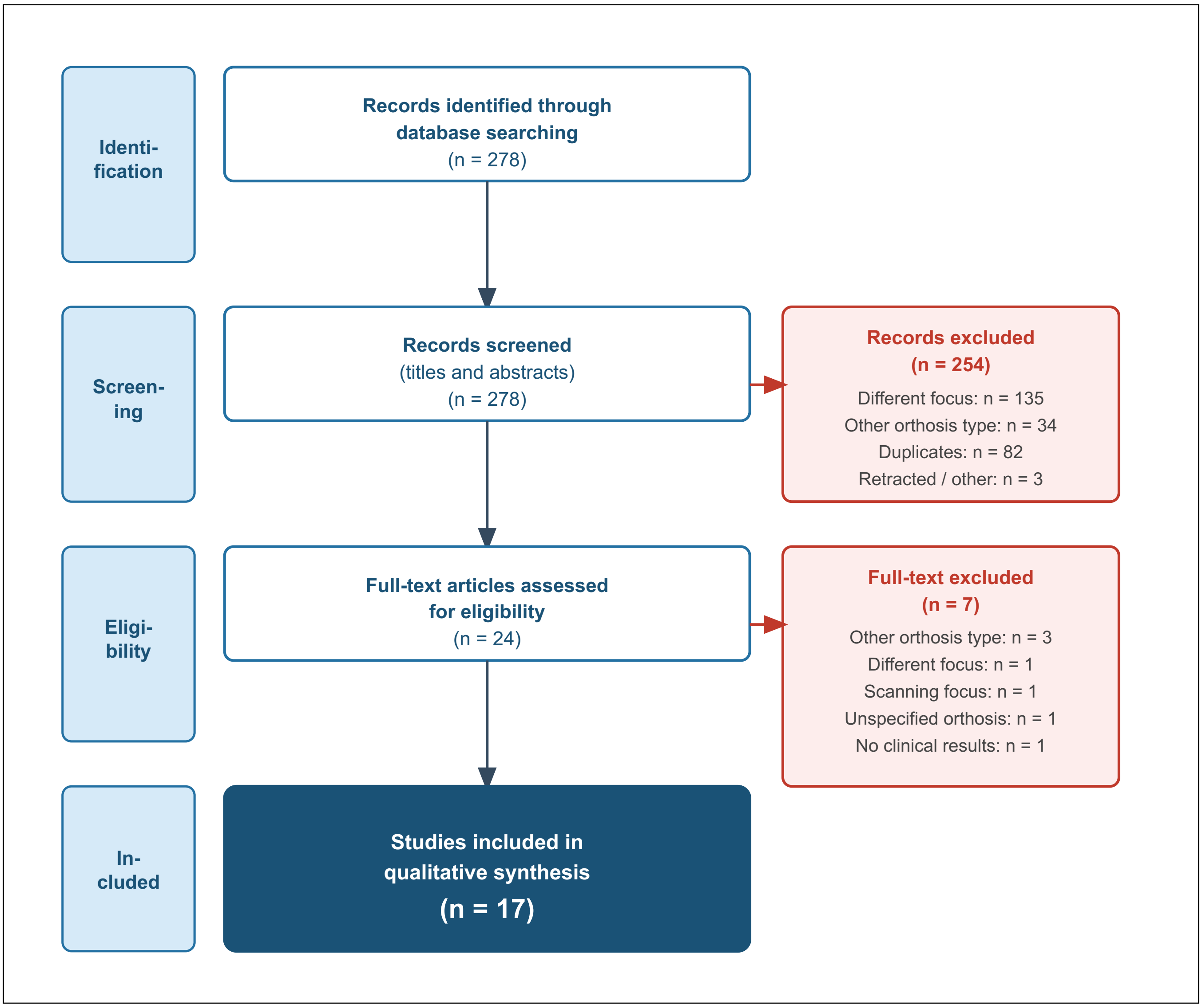

Fig. 1. PRISMA flow diagram of the literature selection process. The search was performed in PubMed with no restriction on the start date, up to January 2026
Picture taken by the authors

ETHICS

This review is based exclusively on the analysis of publicly available scientific data published in peer-reviewed journals, clinical guidelines, and databases. No patient-identifiable data were used, no new clinical interventions were performed, and no primary data collection from patients was conducted. Accordingly, approval from a local ethics committee was not required.

The authors affirm adherence to the ethical principles of the Declaration of Helsinki of the World Medical Association and to international standards of publication ethics, including the recommendations of the International Committee of Medical Journal Editors (ICMJE). No elements of this work contain plagiarism, fabrication, or falsification of data. All sources of information are correctly cited and properly formatted.

REVIEW AND DISCUSSION

The 3D printing techniques utilized included selective laser sintering (SLS), fused deposition modelling (FDM), fused filament fabrication (FFF), stereolithography (SLA), and multi-jet fusion (MJF). The most frequently used materials were polyamide Nylon 12 (PA12), polylactic acid (PLA), polyamide (PA), and carbon fibre composites. Outcome measures included gait kinematics, kinetics, plantar pressure, spatiotemporal parameters, patient-reported satisfaction, and functional assessments.

GAIT KINEMATICS AND KINETICS

The effects of 3D-printed AFOs on gait kinematics were consistently reported across included studies. Compared to the no-AFO condition (barefoot or shoe-only), 3D-printed AFOs significantly reduced ankle plantarflexion at heel strike, push-off, and during the swing phase, indicating effective control of foot drop and improved foot clearance [15,16]. Ankle dorsiflexion during the swing phase was increased, supporting the primary functional goal of AFO application.

Hip flexion at heel strike was increased with 3D-printed AFOs compared to the no-AFO condition, suggesting enhanced proximal joint stability. The knee flexor moment between 35% and 60% of the stance phase was increased [15, 17]. Wojciechowski et al. demonstrated that 3D-printed AFOs made from PA12 were biomechanically comparable to conventional AFOs for children with Charcot-Marie-Tooth (CMT) and were approximately one-third lighter, a significant practical advantage [18].

When compared directly with conventionally manufactured AFOs, the 3D-printed devices demonstrated equivalent kinematic outcomes across most parameters, including peak hip flexion, hip joint moments, knee flexion, and ankle plantarflexor moment [15, 18]. Some studies reported that redesigned 3D-printed AFOs with modified geometry provided superior ankle dorsiflexion at heel strike and during swing, attributed to design innovations enabled by additive manufacturing [18].

Cha et al. described the design and clinical application of a 3D-printed AFO manufactured using automated CAD software (MediACE3D®, SolidEng Corp.) combined with 3D scanning (Artec Eva) in a single patient — a 68-year-old woman with foot drop secondary to common peroneal neuropathy. The AFO was fabricated using a fused filament fabrication (FFF) printer with thermoplastic polyurethane (TPU) filament. A mechanical durability test of 300,000 loading cycles (simulating approximately 4 months of use) demonstrated no cracking or structural deformation. Gait analysis showed that both the conventional polypropylene AFO and the 3D-printed AFO equally improved walking speed from 42.2 cm/s (without AFO) to 56.5 cm/s. Single stance symmetry was highest with the 3D-printed AFO (80.4%), followed by the conventional AFO (79.7%), and lowest without an AFO (69.7%). The conventional AFO provided slightly greater ankle dorsiflexion during swing phase due to higher rigidity. According to the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST), the patient was more satisfied with the 3D-printed AFO in terms of weight and ease of use (total QUEST score: 4.5 vs. 4.1), while rating the conventional AFO as more effective due to the flexible material of the 3D-printed device causing some foot drop during swing [19].

PLANTAR PRESSURE DISTRIBUTION

The customization of AFOs using 3D printing was associated with improved plantar pressure distribution. Studies reported significant reductions in peak plantar pressure at the rearfoot, forefoot, and total plantar surface when wearing 3D-printed AFOs compared to shoe-only conditions [15, 18, 20]. In a well-powered RCT by Xu et al. (n=60, plantar fasciitis), 3D-printed AFOs led to significantly lower peak plantar pressure in the heel and midfoot regions and substantially reduced pain compared to standard orthoses, confirming the biomechanical benefits of individualized 3D-printed design [14].

SPATIOTEMPORAL PARAMETERS

Spatiotemporal gait parameters, including stride length, walking velocity, cadence, and stance time, were consistently improved with 3D-printed AFOs compared to the no-AFO condition across multiple studies [14, 16, 21, 22]. The spatiotemporal parameters measured with 3D-printed AFOs were generally equivalent to those achieved with conventional AFOs, with no statistically significant differences in stride length, cadence, stance time, or gait velocity in the majority of comparative studies [16, 18].

Qin et al. conducted a retrospective cohort study at Guigang People's Hospital (China), reviewing medical records of 124 children (aged 3–6 years) diagnosed with spastic cerebral palsy (GMFCS level I–II), treated between January 2022 and June 2024. Sixty-two children received customized 3D-printed AFOs (aluminum alloy upper combined with TPU95A sole), and 62 received traditional polyethylene AFOs. Both groups underwent identical 3-month standardized rehabilitation programmes. At 3-month follow-up, the 3D-printed AFO group demonstrated significantly superior outcomes: Gross Motor Function Measure (GMFM) scores (74.98 ± 3.42 vs. 69.08 ± 2.95, $p=0.001$), step length (31.15 ± 4.18 vs. 28.68 ± 4.32 cm, $p=0.01$), walking speed (0.56 ± 0.10 vs. 0.52 ± 0.12 m/s, $p=0.022$), and step width (14.52 ± 2.36 vs. 15.82 ± 2.40 cm, $p=0.011$). Passive ankle dorsiflexion angle also showed greater improvement in the treatment group ($p=0.027$). The 3D-printed AFOs were significantly lighter (123.6 ± 36.15 g vs. 183.2 ± 65.78 g, $p<0.001$) and thinner (1.71 ± 0.17 mm vs. 3.00 mm), which the authors attributed to the use of aluminum alloy and structural optimization, including ventilation holes. No adverse events were reported in either group [23].

FUNCTIONAL MOBILITY AND COMMUNITY AMBULATION

Cho et al. evaluated 3D-printed AFOs in three stroke survivors over a 4-week community ambulation training programme. The orthoses improved step length, gait symmetry, ankle range of motion, and muscle activation efficiency. Patients also demonstrated improved balance, walking endurance, and reduced depressive symptoms [24]. Chae et al. reported that in three clinical cases, 3D-printed orthoses improved functional outcomes, including the 6-minute walk test and daily activity performance, compensating for lost motor function [25].

Amitrano et al. assessed 8 patients and noted that while passive orthoses partially corrected compensatory biomechanical patterns, physical training and gait training with the orthosis remained important complements to device prescription [26].

Chae et al. presented three case reports of patients with peripheral nerve injuries treated with individualized 3D-printed orthoses. The orthoses were designed using MIMICS Medical v17 and Geomagic Freeform software and printed on a FINEBOTZ420 machine. Case 3 involved a patient with right lower lumbar radiculopathy and foot drop, who received a 3D-printed AFO. Following orthotic application, the patient demonstrated improvement in the 6-minute walk test (6MWT) distance, improvement in the modified Emory Functional Ambulation Profile (mEFAP) score, and improved stability assessment scores. Patient satisfaction assessed by the QUEST questionnaire was rated as a perfect score. The authors highlighted that the advantages of 3D-printed orthoses over conventional ones include lower cost, easier modification, and faster fabrication, enabling physicians to create individually tailored products [25].

MECHANICAL PROPERTIES AND STIFFNESS

Choi et al. demonstrated in 8 healthy volunteers that 3D-printed AFOs at varying stiffness levels consistently optimized muscle-tendon function and reduced estimated energy cost during walking [27]. Raj et al. showed that 3D-printed PLA-CF AFOs exhibit higher stiffness and load-bearing capacity compared to standard PLA constructs, confirming mechanical reliability [28]. Ielapi et al. validated a protocol for assessing stiffness and stress distribution in two 3D-printed AFO designs, with modelling accuracy within approximately 10% of experimental results [29].

Swesi et al. investigated the process parameter optimization and mechanical properties of ankle–foot orthoses manufactured by fused filament fabrication (FFF) 3D printing using polypropylene (PP) filament. The study addressed the primary manufacturing challenge of PP — limited bed adhesion and high shrinkage, which is especially problematic for large parts such as AFOs. Through systematic optimization of printing parameters (nozzle temperature, print speed, layer height, infill pattern, and bed adhesion strategies), the authors achieved specimens meeting structural requirements for orthotic applications. PP was identified as a particularly suitable material for AFO fabrication due to its light weight, superior flexibility, chemical resistance, biocompatibility, and long-term durability properties that combine to offer an excellent balance between rigidity and energy return during gait. The findings provide a validated manufacturing framework for producing PP-based custom AFOs using accessible desktop FFF printers [30].

PATIENT SATISFACTION

Patient-reported satisfaction was assessed across several included studies. Lin et al. (2021) reported significantly higher satisfaction with 3D-printed AFOs compared to conventional ones in dimensions of fit, ease of use, comfort, and effectiveness ($p<0.001$) [17]. Fu et al. and Wojciechowski et al. found no statistically significant differences in satisfaction between 3D-printed and conventionally manufactured AFOs, with both types rated comparably in weight, comfort, and ease of use [18, 20]. Cho et al. noted positive qualitative feedback from stroke survivors, who appreciated the lighter weight, thinner profile, and improved gait adjustability [24].

SAFETY PROFILE

Among all 17 studies included in this review, no serious adverse events related to the use of 3D-printed AFOs were reported. Minor issues included transient discomfort during the initial fitting period and one instance of device cracking observed after 6 weeks of use in an SLS-manufactured segmented orthosis [31]. The search of the MAUDE database for the equivalent device manufacturer, Protect 3D Inc. (USA), identified zero adverse events. These findings support a favourable safety profile, with identifiable risks being manageable through clinical monitoring and individualized fitting.

GENERAL DISCUSSION AND CLINICAL IMPLICATIONS

This review synthesizes evidence from 17 clinical and biomechanical studies on custom-made 3D-printed AFOs. The overall findings indicate that these devices are effective, safe, and clinically acceptable for individuals with ankle impairments. The improvements in ankle kinematics, spatiotemporal gait parameters, plantar pressure distribution, and patient-reported satisfaction are consistent with established evidence on conventional AFO efficacy [3, 15, 32].

A key finding of this review is the functional equivalence of 3D-printed AFOs to conventionally manufactured devices across the majority of gait parameters. This equivalence has important clinical implications: 3D-printed AFOs can replace conventional devices without compromising functional outcomes while offering additional advantages, including design flexibility, reduced fabrication time, and improved patient customization. The study by Wojciechowski et al. is particularly noteworthy in this regard, demonstrating that 3D-printed PA12 replicas of traditional AFOs produced equivalent biomechanical outcomes and self-reported satisfaction among children with CMT [18].

The large-sample study by Qin et al. (n=124 children) represents one of the most robust contributions to date in paediatric AFO research, demonstrating significant superiority of 3D-printed AFOs over conventional ones in GMFM scores, stride parameters, and user comfort [23]. Similarly, the RCT by Xu et al. (n=60) provides high-quality evidence for the effectiveness of 3D-printed orthoses in pain management and plantar pressure redistribution [14]. These two studies significantly strengthen the evidence base and should be considered central to future clinical guideline development.

The design-specific benefits of 3D printing deserve particular attention. The ability to precisely control AFO stiffness through strut design has been demonstrated to influence ankle kinematics and kinetics [2, 28, 29]. Stiffer struts reduce both plantarflexion and dorsiflexion ranges of motion, while more compliant struts allow greater ankle mobility with reduced push-off energy loss. These findings highlight the potential for 3D printing to enable evidence-based customization of mechanical properties, a capability practically limited with conventional thermoplastic fabrication.

The material PA12 (Nylon 12), used by the Scientific Park of Additive Technologies, is the most widely tested and clinically validated material for 3D-printed AFOs in the reviewed literature [7, 18]. It offers a favourable combination of mechanical strength, biocompatibility, and patient comfort, and has not been associated with adverse tissue reactions in any included study.

Leith et al. conducted a mixed-methods cross-sectional study investigating the usability of performing clinical adjustments on 3D-printed (PA12, HP Multi Jet Fusion technology) versus traditionally fabricated AFOs. Ten certified orthotists completed 10 standardized adjustment tasks (including strap relocation, cork wedge addition, grinding, flaring, volume reduction, and easing) on 3D-printed AFOs and evaluated usability using the Single Ease Question (SEQ) and System Usability Scale (SUS). Task completion rate was 99%; however, the professional standard completion rate was only 71%, primarily due to aesthetic concerns (discoloration of PA12 after heating or grinding). SEQ scores were significantly lower for the 3D-printed condition in 5 of 10 tasks. The mean SUS score for 3D-printed AFOs was significantly lower than for traditional AFOs (52.25±11.8 vs. 85.50±10.4, $p<0.001$), indicating low perceived usability for adjustment. Thematic analysis identified five main challenge areas: aesthetics, grinding difficulties, heating behaviour (requiring longer heating and more cautious technique), time-consuming adjustments, and concerns about brittleness/microfracture risk. Despite these challenges, orthotists were optimistic about future clinical adoption and proposed solutions, including optimized heat gun techniques, appropriate grinding protocols, postprocessing (dyeing, vapor smoothing, surface coating), and a learning curve with the new material. The authors concluded that current 3D-printed materials require further development in adjustability to be fully equivalent to traditional thermoplastics in clinical practice [33].

LIMITATIONS OF THE CURRENT EVIDENCE

Several limitations must be acknowledged. The majority of included studies had small sample sizes, with 8 of 17 studies including fewer than 5 participants. Heterogeneous patient populations, diverse AFO designs, and varied outcome measures across studies precluded meta-analytic pooling of data. Most studies evaluated immediate gait effects rather than long-term functional outcomes and device durability. Methodological quality was generally rated as "fair" using the Downs and Black checklist, with deficiencies in blinding, allocation concealment, and a priori power calculations [12]. Future research should prioritize large-scale RCTs with standardized outcome measures and follow-up periods of at least 6 months.

CONCLUSIONS

Custom-made 3D-printed ankle-foot orthoses represent an effective, safe, and clinically viable solution for individualized orthopedic management of lower limb impairments. Evidence from 17 reviewed studies demonstrates that 3D-printed AFOs improve lower extremity kinematics and kinetics, plantar pressure distribution, spatiotemporal gait parameters, and patient satisfaction compared to no-AFO conditions, with outcomes equivalent to conventionally manufactured devices.

The material polyamide PA 12, used by the Scientific Park of Additive Technologies (Kyiv, Ukraine), is the most clinically validated material for 3D-printed AFOs, offering excellent biocompatibility, mechanical performance, and user comfort. No serious adverse events were identified in the reviewed clinical literature or in the MAUDE and Derzhliksluzhba adverse event databases.

Future research should prioritize large-scale randomized controlled trials in specific clinical populations, standardized outcome measures, and longer follow-up periods. Establishing consensus reporting standards for 3D-printed AFO studies would enhance the comparability and synthesis of evidence across studies.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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