

SYSTEMATIC REVIEW

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# The current state of 3D-printed orthoses clinical outcomes: a systematic review

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## Abstract

**Introduction** 3D-printing is an emerging technology that is used in the manufacturing of orthotic devices. 3D-printing has many advantages such as improved fit, comfort, effectiveness, and patient satisfaction. While some challenges like durability and material selection remain, the aim of this systematic review is to provide a comprehensive evaluation of the clinical outcomes of 3D-printed orthoses.

**Methods** A search was conducted following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines across six databases (PubMed, Web of Science, EBSCO, Scopus, Cochrane Library, and Sage). Studies on 3D-printed orthoses in human rehabilitation that focused on the clinical outcomes of the device were included. While studies lacking clinical data, 3D-printing details, or focusing on traditional manufacturing methods were excluded. Finally, the risk of bias was assessed using the modified Downs & Black Checklist.

**Results** A total of 1279 studies were identified, with 62 meeting the inclusion criteria. The included studies assessed different 3D-printed orthotic types, including insoles, ankle foot orthoses (AFOs), spinal orthoses, upper-limb orthoses, and helmets. The main clinical outcomes that were analyzed are gait parameters, functional performance, radiographic measurements, comfort, fit, and effectiveness. Studies on 3D-printed insoles demonstrated effective plantar pressure redistribution, and increased comfort. While studies on 3D-printed AFOs showed improvements in gait symmetry and mobility. 3D-printed spinal orthotics showed reductions in Cobb angles and enhanced postural stability in scoliotic patients. While 3D-printed upper-limb orthoses found improved grip strength, spasticity management, and user satisfaction. Finally, studies on 3D-printed helmets for cranial deformities demonstrated improved fit and reduced treatment duration.

**Conclusion** 3D-printed orthoses can enhance gait parameters, functional performance, comfort, fit, and effectiveness, compared to conventional methods. However, limitations such as small sample sizes, lack of standardized assessment methods, and durability concerns must be addressed through further research.

**Keywords** 3D-printing, Rehabilitation, Additive manufacturing, Clinical outcomes.

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## Introduction

3D-printing is becoming more accessible and increasingly used in the medical field [1]. In particular, 3D-printing offers the possibilities for creating orthoses [2]. It is becoming a rising competitor to the conventional procedure of manufacturing orthoses [3]. 3D-printing offers many advantages, including the ability to create personalized custom-fitted orthoses [4], improve fit [5–7], comfort [8–11], effectiveness [12], and patients' satisfaction [4]. It is also cost-effective, reduces the time required for orthotic production [13], and minimizes the waste of materials during production compared to conventional manufacturing techniques [13, 14]. 3D-printing also offers a high degree of precision in both the design and manufacturing stages, which as a result minimizes the risk of human error compared to conventional techniques [15].

A few systematic reviews have explored the use of 3D-printing to produce specific orthoses [16–21]. A review by Lieshout et al. [16] on 3D-printed forearm braces found high patient satisfaction and low complication rates in their users. Schwartz and Schofield [17] examined the use of 3D-printed orthoses for upper extremity musculoskeletal conditions. A review by da Silva et al. [21] on upper limb exoskeletons highlighted the gap between research and real-world use, suggesting future advancements will focus on flexible materials and actuated devices. A review by Pollen et al. [18] about 3D-printed ankle foot orthoses (AFOs) found that 3D-printed AFOs improve gait parameters and patient satisfaction. Finally, two reviews by Daryabor et al. [19] and Chen et al. [20] addressed the impact of 3D-printed insoles on individuals with flat feet.

However, no review has ever been focused only on clinical outcomes of 3D-printed orthoses. Moreover, to the authors' knowledge, existing systematic reviews have focused each on one orthotic type, leaving a gap in understanding the broader clinical outcomes of this technology. Therefore, the motivation behind this review lies in the growing clinical interest in understanding whether 3D-printed orthoses provide tangible improvements in patient outcomes across various conditions and orthotic types. Existing reviews focus narrowly on specific orthotic types. This gap can be addressed by comprehensively synthesizing the current evidence on clinical performance metrics such as gait parameters, functional performance, radiographic measurements, comfort, fit, and overall effectiveness to inform both clinical decision-making and future research.

## Methods

### Study team

To attain findings that are clinically robust and relevant, the inter-professional team for this study encompassed

individuals with expertise in evidence synthesis, quantitative research methodology, prosthetics and orthotics, occupational therapist, and rehabilitation physician.

### Search strategy and data sources

A systematic search was conducted from database inception to January 2025 in compliance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (PRISMA) guidelines, and the study protocol was registered in PROSPERO (no. CRD42024611342). Data were collected from six databases: PubMed, Web of Science, EBSCO, Scopus, Cochrane Library, and Sage. Additionally, a manual search was conducted by reviewing reference lists of identified studies and searching Google Scholar to ensure the inclusion of all relevant articles. A list of keywords used are provided in *Supplementary Table 1*.

### Study selection and eligibility criteria

After accounting for duplication, relevant titles and corresponding abstracts from the search results were imported into an Excel sheet. The selection of included studies was completed over two stages. Initially, identified studies were independently screened for eligibility based on the title and abstract by two authors (H.A and T.Q); at this stage, any discrepancies in opinion were arbitrated by a third author (H.R.B). Secondly, the full texts of eligible studies were screened according to the criteria listed in Table 1. Any disagreements at this stage were independently arbitrated by the third (H.R.B) and fourth (G.F) authors.

#### Inclusion criteria:

- Studies involving human participants using 3D-printed orthotic devices.
- Studies reporting at least one measurable clinical outcome (e.g., gait parameters, pain scores, radiographic changes).
- Randomized controlled trials, cohort studies, case series, and observational studies.

#### Exclusion criteria:

- Studies focusing only on design processes or mechanical testing without clinical data.
- Animal or in-vitro studies.
- Studies using non-3D-printed orthoses or traditional manufacturing techniques.
- Reviews, commentaries, and conference abstracts without full data.

### Data extraction, synthesis and analysis

The following data were extracted: authors, year of publication, aim, methods, results, and conclusions. Data

**Table 1** 3D-printed insoles

Author	Year	Aim	Methods	Results	Conclusion
Maharana et al. [23]	2022	Develop and test 3D-printed insoles with snapping arch structures to offload high-pressure areas in the foot.	<ul style="list-style-type: none"> <li>Participants: 100 categorized as neuropathic (<math>n = 71</math>) and nonneuropathic (<math>n = 29</math>). (Genders were not specified).</li> <li>Mean age of participants: 55 years</li> <li>Tools: Plantar pressure measurement system.</li> <li>Measures: Pressure distribution on the foot's sole.</li> <li>Methods: A 3D-printed thermoplastic polyurethane (TPU) insole was tested and compared with barefoot and in-shoe plantar pressure measurements.</li> </ul>	<ul style="list-style-type: none"> <li>The 3D-printed insole reduced forefoot plantar pressure more effectively than barefoot and standard in-shoe conditions.</li> </ul>	3D-printed insoles with snapping arches effectively reduce plantar pressure in patients with diabetic peripheral neuropathy, potentially preventing related complications.
Smadici et al. [13]	2022	Create a 3D-printed insole using flexible materials, tailored to the participant's foot anatomy, to address uneven plantar pressures identified through static and dynamic analyses.	<ul style="list-style-type: none"> <li>Participants: 12 (7 females, 5 males) with no known pathologies.</li> <li>Mean age of participants: not provided</li> <li>Tools: Plantar pressure measurement system.</li> <li>Measures: Fit and effectiveness of different infill densities in alleviating high plantar pressures.</li> </ul>	<ul style="list-style-type: none"> <li>The 3D-printed insole effectively addressed foot deformities by adjusting heights and thicknesses across the arches, while also reducing high plantar pressures.</li> </ul>	3D-printed insoles improve efficiency, outcomes, and design, while offering a cost-effective alternative to traditional methods.
Muir et al. [24]	2022	Investigate the effect of standard of care (SoC), hybrid 3D-printed insoles with a bilaminar foam top (Hybrid), and full 3D-printed insoles (Full) on walking plantar pressure in adults without ulcers or deformities.	<ul style="list-style-type: none"> <li>Participants: 12 (4 females, 8 males) were included in the final analysis, reduced from 14 after one participant dropped out and one excluded due to a technical issue. The group had no active ulcers or neuropathy, though 3 participants had diabetes</li> <li>Mean age of participants: 63 years</li> <li>Tools: Pressure measurement system.</li> <li>Measures: Plantar pressure data during walking trials for each footwear condition (Research shoe (RS) (shoes with no custom insole), SoC, Hybrid, and Full insoles), and Pressure-Time Integral.</li> </ul>	<ul style="list-style-type: none"> <li>Hybrid and Full 3D-printed insoles reduced maximum peak plantar pressure and Pressure-Time Integral (PTI) in offloading regions.</li> <li>The SoC insoles showed no reduction compared to the research shoe (shoes with no custom insole).</li> </ul>	3D-printed insoles reduce plantar pressure more effectively than standard insoles, without significantly increasing pressure in adjacent areas, and allow for targeted adjustments based on pressure data and patient-specific modeling.
Jin et al. [75]	2019	Assess the impact of a 3D-printed insole with heel and arch support on gait and comfort.	<ul style="list-style-type: none"> <li>Participants: 30 healthy males.</li> <li>Groups: Experimental group A (3D-printed insole with arch support), experimental group B (3D-printed insole with heel support), and control group (pre-made insole with heel support).</li> <li>Mean age of participants: 21 years</li> <li>Tools: Foot scan system.</li> <li>Measures: Peak pressure, contact area, and gait parameters.</li> </ul>	<ul style="list-style-type: none"> <li>The mid-foot contact area significantly increased with both 3D-printed insoles compared to the control.</li> <li>Peak pressures in the heel region were notably reduced with the 3D-printed insoles.</li> <li>Forefoot and mid-foot pressures remained unchanged in all groups.</li> <li>The percentage of force-time integrals for the forefoot was lower with the 3D-printed insoles.</li> <li>Medial-lateral center of pressure (COP) velocity was significantly lower in the forefoot contact phase with the 3D-printed insole with arch support, indicating improved stability.</li> </ul>	A 3D-printed insole with heel and arch support improves biomechanical performance by enhancing plantar pressure distribution and stability, reducing peak pressures in the heel and mid-foot, and effectively managing forefoot load, offering a promising advancement in orthopedic insole design.

**Table 1** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Chhikara et al. [26]	2023	Develop and evaluate the effectiveness of a 3D-printed insole in reducing plantar foot pain and improving functional ability.	<ul style="list-style-type: none"> <li>Participants: 36 females with chronic plantar foot pain.</li> <li>Groups: Experimental (18 using 3D-printed insoles) and control (18 using standard insoles)</li> <li>Mean age of participants: 26 years</li> <li>Tools: Visual Analog Scale (VAS), Foot and Ankle Ability Measure (FAAM) questionnaire, plantar pressure measurement system</li> <li>Measures: Pain levels, functional ability, and plantar pressure while standing and walking</li> </ul>	<ul style="list-style-type: none"> <li>After four weeks, pain reduction was greater in the experimental group compared to the control group.</li> <li>Functionality improvement was higher in the experimental group than in the control group.</li> <li>Pressure while standing and walking decreased more in the experimental group than in the control group.</li> </ul>	3D-printed insoles effectively reduce pain and plantar pressures while improving functionality for individuals with plantar foot pain. This approach shows promise as a conservative management option for those in occupations requiring prolonged standing.
Xu et al. [27]	2019	Investigate the impact of 3D-printed insoles on plantar pressure distribution and comfort.	<ul style="list-style-type: none"> <li>Participants: 80 (40 females, 40 males) with symptomatic flat feet.</li> <li>Groups: Control (standardized shoes with pre-fabricated insoles), Experimental (standardized shoes with 3D-printed insoles).</li> <li>Mean age of participants: Control group (41), Experimental group (38).</li> <li>Tools: Foot scan, motion capture system, Visual Analog Scale (VAS), and comfort scale.</li> <li>Measures: Plantar pressure parameters and comfort at baseline and after 8 weeks.</li> </ul>	<ul style="list-style-type: none"> <li>At week 0, the experimental group exhibited lower peak pressure in the metatarsals and higher peak pressure in the mid-foot compared to the control group.</li> <li>By week 8, the experimental group showed higher peak pressures in mid-foot compared to the control group.</li> <li>The experimental group reported significantly lower comfort scores than the control group.</li> </ul>	3D-printed insoles reduced pressure on the metatarsals by redistributing it to the mid-foot, helping to mitigate damage caused by symptomatic flat feet. They were also more effective and provided better comfort than pre-fabricated insoles for patients with flat feet.
Sterman et al. [28]	2024	Develop and assess 3D-printed insoles with variable printing times and stiffness to improve plantar pressure distribution.	<ul style="list-style-type: none"> <li>Participants: 6 healthy males.</li> <li>Mean age of participants: 33 years.</li> <li>Tools: Dynamic mechanical testing machine, plantar pressure measurement system, and questionnaire.</li> <li>Measures: Mechanical properties (stress-strain curves and durability), stiffness variability (testing samples with different feed speeds and extrusion rates), pressure distribution, user comfort, and performance.</li> <li>Methods: Participants wore the insoles for 30,000 steps.</li> </ul>	<ul style="list-style-type: none"> <li>Faster 3D-printing reduced insole hardness.</li> <li>Thinner 3D-printed insoles exhibited higher yield strengths, and cyclic loading increased stiffness.</li> <li>Mechanical properties varied with printing parameters, and pressure distribution tests indicated differences between uniform and variable stiffness insoles.</li> <li>User feedback reported high comfort and fit ratings, highlighting benefits in weight and ventilation.</li> </ul>	The technique for 3D-printed insoles enables faster, lighter, and customizable production with variable stiffness using a single material, simplifying recycling and manufacturing. This method allows for precise customization based on foot scans and pressure maps, offering a cost-effective solution for custom-made insoles.
Telfer et al. [29]	2017	Compare the pressure offloading effectiveness of 3D-printed insoles optimized through virtual simulation techniques with traditional shape-based insoles.	<ul style="list-style-type: none"> <li>Participants: 18 reduced from an initial 20 (5 females, 15 males). With Type 2 diabetes with peripheral neuropathy and high plantar pressure; 5 had a history of ulcers.</li> <li>Mean age of participants: 64 years.</li> <li>Tools: Plantar pressure measurement system.</li> <li>Measures: Plantar pressures exerted during walking.</li> <li>Methods: Comparison of results between virtual 3D-printed and traditionally made insoles.</li> </ul>	<ul style="list-style-type: none"> <li>Virtual 3D-printed insoles reduced peak plantar pressures compared to traditionally made insoles.</li> </ul>	3D-printed insoles optimized through virtual simulation significantly reduce peak plantar pressures in individuals at risk of foot ulceration due to diabetes.

**Table 1** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Malki et al. [76]	2024	Assess how 3D-printed rocker midsoles and heel cups, both separately and combined, affect plantar pressure in the heel, forefoot, and toe areas.	<ul style="list-style-type: none"> <li>Participants: 9 (2 females, 7 males) with Diabetes Mellitus with loss of protective sensation (high peak pressure (&gt; 200 kPa) in the heel region).</li> <li>Mean age of participants: 67 years.</li> <li>Tools: Plantar pressure measurement system and treadmill.</li> <li>Measures: Peak pressure (PP) in various foot regions were tested under four conditions (Control (shoe with control insole), Heel-cup (Control shoe with experimental insole), Rocker (Rocker shoe with control insole), and Rocker-heel-cup (Rocker shoe with experimental insole)).</li> </ul>	<ul style="list-style-type: none"> <li>In the proximal heel region, heel-cup and rocker-heel-cup insoles significantly reduced plantar pressure compared to the rocker insole, but not to the control insole.</li> <li>The rocker insole increased peak plantar pressure compared to the control insole.</li> <li>In the distal heel, heel-cup and rocker-heel-cup insoles reduced peak plantar pressure compared to both the control and rocker insoles.</li> <li>For the medial forefoot, central forefoot, and other toes, rocker-heel-cup insoles significantly reduced peak plantar pressure compared to both the control and heel-cup insoles.</li> <li>The rocker insole reduced peak plantar pressure in the lateral forefoot compared to both the control and heel-cup insoles, but not in the hallux.</li> </ul>	The combination of a new insole design and a 3D-printed rocker midsole effectively reduced plantar pressure in the distal heel, forefoot, and toes. Further reduction in proximal heel pressure may be achievable with more flexible midsole materials.
Xu et al. [9]	2019	Compare the biomechanical effects and comfort levels of 3D-printed and prefabricated insoles in individuals with plantar fasciitis.	<ul style="list-style-type: none"> <li>Participants: 60 (30 females, 30 males) with bilateral plantar fasciitis with a heel pain score of 3 or greater on a 10-point Visual Analog Scale.</li> <li>Groups: Control (prefabricated insoles) and experimental (3D-printed insoles).</li> <li>Mean age of participants: 45 years.</li> <li>Tools: Plantar pressure measurement system.</li> <li>Measures: Maximum pressure, strength, and contact area (hallux, toes, metatarsals, midfoot, and heel), assessed at weeks 0 and 8.</li> </ul>	<ul style="list-style-type: none"> <li>At week 0, the experimental group exhibited higher peak pressures in the hallux and first metatarsal regions, and lower pressures in the mid-heel and lateral heel regions compared to the control group.</li> <li>By week 8, peak pressures were more evenly distributed in both groups. However, the experimental group reported significantly lower comfort scores.</li> </ul>	3D-printed insoles are effective in reducing plantar pressure, thereby improving comfort compared to prefabricated insoles.
Ning et al. [31]	2022	Compare the effects of Polyurethane (PU), 3D-printed TPU, textile, and leather insoles on heat, humidity, and thermal comfort.	<ul style="list-style-type: none"> <li>Participants: 21 healthy females.</li> <li>Mean age of participants: 25 years.</li> <li>Tools: Skin temperature and humidity sensors, subjective assessments.</li> <li>Measures: Heat, humidity, and thermal comfort.</li> <li>Methods: Foot skin temperature and humidity were recorded during a 30-minute treadmill walk, followed by subjective evaluations of heat, moisture, and insole thermal comfort.</li> </ul>	<ul style="list-style-type: none"> <li>No significant changes in foot skin temperature were observed among all insole types.</li> <li>Textile insoles significantly reduced relative humidity at the sole and heel compared to other insole types.</li> </ul>	Textile insoles provide better moisture management and comfort than other insoles, which showed no significant differences in skin temperature.
Walker et al. [10]	2023	Compare the comfort of novel 3D-printed insoles with variable hardness to prefabricated and traditionally made insoles in a walking study.	<ul style="list-style-type: none"> <li>Participants: 20 healthy males.</li> <li>Mean age of participants: 21 years.</li> <li>Test conditions: 3D-printed, traditionally made, and prefabricated insoles.</li> <li>Tools: Visual analogue scale (VAS), Orthotics Prosthetics User Survey (OPUS), and Pedometer.</li> <li>Measures: Comfort (forefoot, heel, arch, overall orthosis, and shoe fit), daily wear, and step counts.</li> <li>Methods: Groups were compared based on comfort, acceptance, and regional comfort at three time points (0, 1, and 2 weeks).</li> </ul>	<ul style="list-style-type: none"> <li>On Day 1, the prefabricated insoles were rated lower in comfort for forefoot, heel, and arch support vs. traditionally made and 3D-printed insoles.</li> <li>Overall comfort for prefabricated insoles was like others but still ranked lowest.</li> <li>By Days 7 and 14, there were no significant differences in comfort between traditionally made and 3D-printed insoles.</li> </ul>	3D-printed insoles are more comfortable than prefabricated insoles, with increasing comfort over time. They show promise as an alternative to traditionally made designs, with advantages in manufacturing efficiency.

**Table 1** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Channan et al. [32]	2022	Evaluate the effects of the hardness of 3D-printed silicone arch supports.	<ul style="list-style-type: none"> <li>Participants: 12 healthy participants (10 females, 2 males).</li> <li>Mean age of participants: 31 years.</li> <li>Tools: Plantar Pressure Measurement System and Comfort Perception Questionnaire</li> <li>Measures: Plantar pressure distribution (before, immediately after, and one month after the intervention) and comfort perception</li> <li>Methods: Two 3D-printed silicone arch supports of varying hardness (A and B) were compared to a prefabricated arch support (C).</li> </ul>	<ul style="list-style-type: none"> <li>After 1 month, all arch supports increased mid-foot pressure and decreased forefoot and hindfoot pressure.</li> <li>No significant differences in pressure distribution were observed between 3D-printed and prefabricated arch supports.</li> <li>3D-printed silicone medial arch supports were reported as more comfortable compared to the prefabricated ones.</li> </ul>	Material hardness did not affect plantar pressure distribution. The 3D-printed arch supports were more comfortable than the prefabricated ones.
Hsu et al. [33]	2022	Fabricate three types of 3D-printed insoles and compare their biomechanical effects on the lower extremities of participants with flat feet.	<ul style="list-style-type: none"> <li>Participants: 10 (5 females, 5 males) with functional flat foot, confirmed by a Foot Posture Index (FPI) score of <math>\geq 6</math>.</li> <li>Mean age of participants: 30 years.</li> <li>Tools: Motion capture system and force plates.</li> <li>Measures: Navicular height, kinetics, kinematics, and comfort scales.</li> <li>Methods: Data were recorded during walking under four conditions: no insoles (shoe), auto-scan insoles (scan), total contact insoles (total), and wedge insoles (wedge).</li> </ul>	<ul style="list-style-type: none"> <li>All 3D-printed insoles improved ankle movements.</li> <li>All 3D-printed insoles enhanced navicular height, dorsiflexion, and comfort scores.</li> <li>Total contact insoles reduced ankle eversion during mid-stance, while knee moment remained unchanged compared to the other 3D-printed insoles.</li> </ul>	The three 3D-printed insoles improved arch support, ankle dorsiflexion, and comfort. The 3D-printed wedge insole showed the best results for ankle joint deformity correction compared to the other 3D-printed insoles.
Cheng et al. [34]	2021	Evaluate 3D-printed insoles with reinforced stiffness and an undercut height in the arch support for flat feet.	<ul style="list-style-type: none"> <li>Participants: 10 (6 females, 4 males) with flexible flat foot, confirmed by a plantar arch index greater than 0.9.</li> <li>Mean age of participants: 20 years.</li> <li>Tools: Motion capture system.</li> <li>Measures: Kinematics, kinetics, and plantar pressure parameters.</li> <li>Methods: A randomized crossover trial compared four conditions: no insole, 3D-printed insoles with reinforcement and undercut arch support, reinforcement only, and undercut arch support only.</li> </ul>	<ul style="list-style-type: none"> <li>3D-printed insoles improved ankle joint dorsiflexion and medial midfoot pressure, while reducing hindfoot pressure.</li> <li>3D-printed insoles showed no significant effects on controlling hindfoot eversion and forefoot abduction.</li> <li>The strongest insole (reinforcement and undercut arch support) didn't always perform better, likely due to over-cutting.</li> </ul>	3D-printed insoles improved midfoot pressure, ankle dorsiflexion, and offloaded the hindfoot. The performance of the reinforced and undercut arch support insole was inconsistent, likely due to over-cutting.
Wang et al. [35]	2021	Assess the effectiveness of 3D-printed insoles in treating flat feet.	<ul style="list-style-type: none"> <li>Participants: 50 (31 females, 19 males) reduced from an initial of 64. Participants had both symptomatic and asymptomatic flexible flat foot, with two cases identified as semi-rigid flatfoot.</li> <li>Mean age of participants: 26 years.</li> <li>Tools: American Orthopedic Foot and Ankle Society (AOFAS) scoring system, 3D foot scanner, clinical examination, telephone follow-up.</li> <li>Measures: Foot function and symptom relief, duration of daily use, clinical symptoms (arch collapse, foot pain, backward foot), gait parameters, and patient feedback on comfort.</li> </ul>	<ul style="list-style-type: none"> <li>AOFAS scores improved significantly after one year.</li> <li>The persistence rate for using the insoles increased.</li> <li>Reasons for abandonment included discomfort (9 cases) and perceived ineffectiveness.</li> </ul>	3D-printed insoles effectively treat flexible flat feet, emphasizing the importance of personalization, patient adherence, and follow-ups for optimal comfort and support.

**Table 1** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Ho et al. [36]	2022	Compare the effects of 3D-printed and traditionally made insoles on foot biomechanics during walking.	<ul style="list-style-type: none"> <li>Participants: 13 (8 females, 5 males) with unilateral plantar fasciopathy (heel pain for more than 3 months) and flat feet (Foot Posture Index score &gt; +6).</li> <li>Groups: 3D-printed insoles, traditionally made insoles, and no insoles (control).</li> <li>Mean age of participants: ≥ 18 years</li> <li>Tools: Motion capture system.</li> <li>Measures: Gait parameters.</li> </ul>	<ul style="list-style-type: none"> <li>3D-printed insoles reduced arch height drop compared to traditionally made insoles.</li> <li>Both 3D-printed and traditionally made insoles had significant effects on ankle moment and power compared to the control group, with no differences between the two types of insoles.</li> </ul>	3D-printed insoles are more effective than traditionally made insoles in reducing arch height drop. Both types reduce ankle plantarflexion moment and power compared to no insoles, with 3D-printed insoles being equally effective for individuals with flat feet and unilateral heel pain.
Öztürk and Kurul [37]	2024	Evaluate the effects of 3D-printed insoles on physical activity levels, balance, and functional performance.	<ul style="list-style-type: none"> <li>Participants: 38 (15 females, 23 males) with bilateral pes planus (subtalar pronation angle of ≥ 5 degrees and a Foot Posture Index (FPI) score of ≥ +6).</li> <li>Groups: 3D-printed insole and placebo groups.</li> <li>Mean age of participants: 3D-printed insole group (24), placebo group (23).</li> <li>Tools: Foot Posture Index, Goniometer, Hand Dynamometer, Flamingo Balance Test, Y-Balance Test, Standing Long Jump Test, Shuttle Running Test, 10-Meter Walk Test, Heel Raise Test, International Physical Activity Questionnaire (IPAQ), and Pedobarographic measurements.</li> <li>Measures: Gait parameters.</li> </ul>	<ul style="list-style-type: none"> <li>The 3D-printed insole group improved significantly in plantar flexion, dorsiflexion, balance, and walking.</li> <li>The placebo group showed significant changes in RoM, running, heel raise, and activity.</li> <li>The 3D-printed group excelled in balance and running, while the placebo group showed better physical activity.</li> </ul>	3D-printed insoles significantly improved muscle strength, dynamic balance, and tibialis posterior muscle endurance in patients with pes planus. These benefits are likely due to be enhanced in sensory input and improved foot biomechanics. In contrast, the placebo group's improvements are attributed to psychological factors and increased physical activity.
Desmytere et al. [38]	2021	Evaluate the impact of 3D-printed insoles stiffness and a newly designed rear-foot posting on lower-limb kinematics and kinetics in individuals with flat feet.	<ul style="list-style-type: none"> <li>Participants: 19 (13 females, 6 males) with painful flexible flat feet.</li> <li>Mean age of participants: 37 years.</li> <li>Tools: Motion capture system and treadmill.</li> <li>Measures: Discomfort ratings with visual analogue scales (VAS), kinematic, kinetic, and plantar pressure.</li> </ul>	<ul style="list-style-type: none"> <li>Stiffness of 3D-printed insoles had minimal impact on mid-foot and forefoot biomechanics.</li> <li>Rigid 3D-printed insoles have reduced mid-foot eversion and forefoot abduction during short stance phases.</li> <li>3D-printed postings significantly affected rear-foot kinematics and ankle/knee kinetics, reducing ankle eversion angle and inversion moment, while increasing knee abduction moment.</li> </ul>	Adding anti-pronator components to 3D-printed insoles is more effective than altering orthotic stiffness for changing gait patterns in flat feet. 3D-printed postings reduce rear-foot eversion, ankle inversion moment, and increase knee abduction moment, improving control of excessive foot pronation.
Jin et al. [25]	2019	Assess the impact of different one-sided insoles on balance during standing and gait asymmetry immediately after use.	<ul style="list-style-type: none"> <li>Participants: 30 healthy males.</li> <li>Groups: Experimental group (3D-printed lateral wedge insole), Experimental group B (Standard lateral wedge insole), and control group (flat-foot insole), all on the left side.</li> <li>Mean age of participants: 20 years.</li> <li>Tools: Motion capture system.</li> <li>Measures: Gait parameters.</li> </ul>	<ul style="list-style-type: none"> <li>Experimental groups A and B exhibited immediate asymmetric posture and gait compared to the control group.</li> <li>After 20 min, the standard lateral wedge insole did not significantly affect posture or gait, while the 3D-printed lateral wedge insole caused persistent asymmetry.</li> <li>The center of pressure was significantly higher in experimental group A compared to groups B and control</li> </ul>	A customized 3D-printed lateral wedge insole can quickly induce posture and gait asymmetry, suggesting its potential effectiveness in gait rehabilitation for addressing alignment issues.

**Table 1** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Man-nisi et al. [39]	2019	Investigate the immediate effect of 3D-printed lateral wedge insoles (LWIs) on medial compressive force (MCF).	<ul style="list-style-type: none"> <li>Participants: 15 (7 participants 5 males, 2 females with medial knee osteoarthritis and varus alignment) and (8 healthy participants 3 males, 5 females).</li> <li>Mean age of participants: Healthy participants (56), KOA participants (62).</li> <li>Tools: Subject-specific musculoskeletal model, motion capture system, and 3D-printed lateral wedge insoles (LWIs).</li> <li>Measures: Medial compressive force while walking with 3D-printed LWIs at different degrees of wedging (0°, 5°, 10°), and baseline measurements.</li> </ul>	<ul style="list-style-type: none"> <li>3D-printed lateral wedge insoles (LWIs) did not reduce the peak or impulse of the medial compressive force (MCF) and did not consistently shift the load from the medial to the lateral knee compartment.</li> <li>3D-printed LWIs with different degrees of wedging had no effect on the MCF.</li> <li>3D-printed LWIs resulted in high inter-subject variability in terms of MCF impulse range and peak.</li> </ul>	3D-printed lateral wedge insoles (LWIs) did not significantly reduce the medial compressive force (MCF) in patients with medial knee osteoarthritis and had no consistent effect across different wedging angles. The high variability in individual responses suggests that further research is needed to optimize these insoles.
Lin et al. [40]	2021	Assess the effects of 3D-printed insoles.	<ul style="list-style-type: none"> <li>Participants: 15 (13 females, 2 males) with medial knee osteoarthritis (OA) with a Kellgren–Lawrence grade of I or II.</li> <li>Mean age of participants: 60 years.</li> <li>Tools: Motion capture system and force plates.</li> <li>Measures: Gait parameters.</li> </ul>	<ul style="list-style-type: none"> <li>There is no significant difference in walking speed between the conditions.</li> <li>The center of pressure shifted laterally with the shoe and 3D-printed insoles compared to the shoe only.</li> <li>Peaks of knee adduction moments and ankle inversion moments decreased with the shoe and 3D-printed insoles compared to the shoe only.</li> <li>No significant changes were observed in peak knee flexion moment or ankle eversion moment.</li> </ul>	3D-printed insoles have reduced peak ankle inversion and knee adduction moments, thereby lowering knee joint loading in patients with osteoarthritis, making them a viable conservative treatment.
Desmytere et al. [41]	2020	Determine the effect of 3D-printed insoles stiffness and newly design of rear-foot postings on foot kinematics and plantar pressures in healthy people.	<ul style="list-style-type: none"> <li>Participants: 15 healthy males.</li> <li>Mean age of participants: 24 years.</li> <li>Tools: Motion Capture and plantar pressure measurement systems.</li> <li>Measures: Foot kinematics and plantar pressures.</li> </ul>	<ul style="list-style-type: none"> <li>Increasing the stiffness of 3D-printed insoles alters frontal and transverse plane foot kinematics, reducing rear-foot eversion, increasing rear-foot abduction, and raising peak pressures under the rear-foot and mid-foot.</li> <li>The new design of the 3D-printed rear-foot postings enhances rear-foot frontal plane kinematics and shifts loads from the rear-foot to the mid-foot.</li> </ul>	3D-printed insoles allow clinicians to customize foot orthoses with various materials and designs for specific pathologies, with adjustments during treatment.
Telfer et al. [42]	2013	Evaluate how 3D-printed insoles with varying rear-foot post angles affect lower-limb mechanics.	<ul style="list-style-type: none"> <li>Participants: Participants: 24.</li> <li>Groups: Patients (12 participants 6 females, 6 males with pronated feet confirmed by a Foot Posture Index (FPI) and a relaxed calcaneal stance position of &gt; 4° everted) and controls (12 participants 6 females, 6 males with normal feet).</li> <li>Mean age of participants: Patients (28), Controls (31).</li> <li>Tools: Motion capture system and force plates</li> <li>Measures: Gait parameters.</li> </ul>	<ul style="list-style-type: none"> <li>3D-printed insoles with a higher medial rear-foot post angle reduced rear-foot eversion and decreased ankle eversion moments. They increased peak and mean knee adduction moments.</li> <li>No significant differences were observed between symptomatic pronated and asymptomatic normal foot types.</li> </ul>	3D-printed insoles with medial postings increase knee adduction moments, potentially worsening knee osteoarthritis in individuals with normal foot types.

**Table 1** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Zhang and Vanwanseele [43]	2023	Assessing the impact of varying levels of 3D-printed forefoot wedge insoles (FFWIs) on jogging kinematics and arch support.	<ul style="list-style-type: none"> <li>Participants: 12 (5 females, 7 males) recreational runners with symptomatic pronated feet confirmed by a Foot Posture Index (FPI) score of <math>\geq 6</math>.</li> <li>Mean age of participants: 25 years.</li> <li>Tools: Ten pairs of 3D-printed insoles with five levels of forefoot wedges and two levels of arch support, along with a motion capture system.</li> <li>Measures: Gait parameters.</li> </ul>	<ul style="list-style-type: none"> <li>Increasing the level of 3D-printed forefoot wedge insoles (FFWIs) had linear effects on foot kinematics during jogging, reducing forefoot peak dorsiflexion, eversion, and rear-foot peak dorsiflexion.</li> <li>Medial 3D-printed FFWIs reduced forefoot peak abduction.</li> <li>Medial 3D-printed FFWIs influenced the sagittal range of motion of both the forefoot and rear-foot in opposing directions.</li> <li>The addition of arch support did not enhance the kinematic performance of the forefoot wedge.</li> </ul>	3D-printed forefoot wedge insoles (FFWIs) have a linear effect on forefoot kinematics during jogging, with a medial forefoot wedge effectively reducing forefoot peak abduction. This suggests that 3D-printed medial forefoot wedges may be beneficial as an anti-pronator component for managing forefoot motion in pronated feet.
Telfer et al. [44]	2013	Evaluate how 3D-printed rear-foot postings affect electromyographic (EMG) activity and plantar pressures in individuals with normal and pronated foot types.	<ul style="list-style-type: none"> <li>Participants: 24.</li> <li>Groups: Patients (12 participants 6 females, 6 males with symptomatic pronated feet) and controls (12 participants 6 females, 6 males with normal feet).</li> <li>Mean age of participants: 29 years.</li> <li>Tools: Electromyography (EMG) and plantar pressure measurement systems, and motion capture systems.</li> <li>Measures: Muscle activity, foot pressure distribution, gait parameters, comfort, and effectiveness.</li> </ul>	<ul style="list-style-type: none"> <li>Significant interaction effects were observed in the gastrocnemius medialis and soleus muscles with 3D-printed insoles compared to normal conditions.</li> <li>Patients exhibited reduced activity in above-knee muscles, including the biceps femoris, vastus lateralis, and vastus medialis, compared to controls.</li> <li>Linear effects were observed with reduced plantar pressure at the lateral rear-foot and mid-foot with the 3D-printed medial posting compared to normal conditions.</li> </ul>	3D-printed insoles did not significantly impact electromyographic (EMG) activity but affected above-knee muscles, as well as the soleus and gastrocnemius medialis. Increased rear-foot posting reduced lateral rear-foot and mid-foot pressure, influencing both pressure distribution and muscle activity.
Shaikh et al. [45]	2023	Develop and assess 3D-printed insoles for managing foot disorders, focusing on comfort, functionality, and pain relief.	<ul style="list-style-type: none"> <li>Participants: 200 with foot-related musculoskeletal ailments (166 with a flat foot, 16 with high arch, 18 with a diabetic/neuropathic foot, and 126 with joint pain). (Genders were not specified).</li> <li>Mean age of participants: 44 years</li> <li>Tools: American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score, plantar pressure measurement systems, 3D scanner, compression tests, and user wear tests.</li> <li>Measures: Pain, function, alignment, plantar pressure distribution, mechanical properties, comfort, and fit.</li> </ul>	<ul style="list-style-type: none"> <li>3D-printed insoles significantly improved AOFAS scores for individuals with flat feet, alleviating joint pain and enhancing comfort and functionality.</li> <li>Diabetic patients experienced pressure relief; however, two discontinued uses of the insoles.</li> </ul>	3D-printed insoles offer effective correction and pain relief, demonstrating good durability over 21 months, except when exposed to moisture. For individuals with higher body weight, replacement after 18 months is recommended. This method is adaptable to various 3D-printing technologies.
Tarrade et al. [46]	2019	Assess the effectiveness of 3D-printed insoles in improving symptoms of musculoskeletal disorders.	<ul style="list-style-type: none"> <li>Participants: 34 (7 females, 27 males) suffering from foot pain due to prolonged standing (with a minimum pain score of 2 on an 11-point scale).</li> <li>Mean age of participants: 43 years</li> <li>Tools: Foot Health Status Questionnaire (FHSQ), Numeric Rating Scale (NRS), pressure measurement system, and force plate.</li> <li>Measures: Changes in pain and comfort levels, plantar pressures, and balance parameters.</li> </ul>	<ul style="list-style-type: none"> <li>3D-printed insoles have significantly improved comfort and reduced pain.</li> <li>Peak plantar pressures notably decreased in the medial mid-foot and rear-foot during both static and dynamic conditions.</li> <li>Balance showed significant improvements, including reductions in total sway displacement and medial-lateral displacement amplitude.</li> </ul>	3D-printed insoles have been shown to alleviate foot pain in workers who stand for extended periods. However, without a control group and a larger sample size, the specific benefits of 3D-printing technology remain unclear, and the placebo effect cannot be ruled out.

**Table 1** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Salles and Gyi [6]	2013	Evaluate the effects of 3D-printed insoles on recreational runners' performance.	<ul style="list-style-type: none"> <li>Participants: 26 healthy participants (13 per group). The study started with 38 runners, but 7 discontinued. (6 males and 7 females) in each of the two groups (12 males and 14 females total)</li> <li>Groups: Experimental (3D-printed insoles) and control (standard insoles).</li> <li>Mean age of participants: Experimental (32), control (34).</li> <li>Tools: Activity diary, 3D laser scanner, Geomagic software, electronic timing gates, plantar pressure measurement system (F-Scan Mobile sensor), motion capture system, Visual Analogue Scale (VAS).</li> <li>Measures: Self-reported discomfort survey (VAS), gait parameters, foot geometry, and insole fit.</li> <li>Time: The insoles were evaluated over a 3-month period.</li> </ul>	<ul style="list-style-type: none"> <li>3D-printed insoles reduced heel discomfort and improved overall fit compared to standard insoles, although arch discomfort was similar in both conditions.</li> <li>3D-printed insoles reduced ankle joint dorsiflexion at foot strike, maximum ankle eversion, and peak heel pressure, while improving comfort and reducing the risk of injury.</li> </ul>	3D-printed insoles with a heel cup and rigid arch support can reduce heel discomfort, improve fit, and decrease ankle joint dorsiflexion and heel pressure.
Mo et al. [47]	2019	Compare the effects of 3D-printed, prefabricated, and no insoles on rear-foot eversion, vertical loading rates, and comfort in female rear-foot strike runners.	<ul style="list-style-type: none"> <li>Participants: 13 females with asymptomatic excessive foot pronation.</li> <li>Mean age of participants: 36 years.</li> <li>Test conditions: 3D-printed insoles, prefabricated insoles, and no insoles.</li> <li>Tools: Treadmill, motion capture system, and Visual Analogue Scale (VAS).</li> <li>Measures: Gait parameters and comfort (medial-lateral control and heel cushioning).</li> </ul>	<ul style="list-style-type: none"> <li>3D-printed and prefabricated insoles significantly reduced peak rear-foot eversion angles compared to no insoles.</li> <li>No significant differences were found in rear-foot eversion at initial contact, eversion velocities, or loading rates.</li> <li>Both 3D-printed and prefabricated insoles improved perceived comfort compared to no insoles.</li> </ul>	3D-printed and prefabricated insoles have improved comfort and reduced peak rear-foot eversion in female recreational runners, with no differences in vertical loading rates. Given the lack of biomechanical or comfort differences, 3D-printed insoles are recommended as a viable alternative for clinical use.
Brogna-ra et al. [48]	2020	Evaluate the impact of acute plantar stimulation with a 3D-printed insole on various gait parameters.	<ul style="list-style-type: none"> <li>Participants: 24 (14 females, 10 males).</li> <li>Groups: Experimental (12 participants 6 females, 6 males with Parkinson's disease (PD) and control (12 participants 8 females, 4 males with other neurological disorders).</li> <li>Mean age of participants: Experimental group (80), control group (82) years.</li> <li>Tools: Inertial Measurement Units (IMUs), Barthel Index, Tinetti Performance-Oriented Mobility Assessment (POMA) scale, Geriatric Depression Scale (GDS), Mini-Mental Status Examination (MMSE), and Unified Parkinson's Disease Rating Scale (UPDRS III).</li> <li>Measures: Gait parameters, functional and cognitive assessments, Parkinson's disease-specific evaluations, and motor symptoms and disease severity.</li> </ul>	<ul style="list-style-type: none"> <li>Patients with PD exhibited significantly greater gait asymmetry, variability, and pitch contact compared to patients with other neurological disorders.</li> <li>Plantar stimulation eliminated these differences in the PD group, aligning gait parameters with those of the control group.</li> <li>Stride length increased significantly in both groups, while no significant changes were observed in other gait parameters.</li> </ul>	3D-printed insoles improved gait stability, reduced stride asymmetry, and increased stride length in patients with Parkinson's disease.

**Table 1** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Brogna et al. [49]	2022	Assess the effects of acute mechanical plantar stimulation using 3D-printed insoles on gait and postural parameters in older adults.	<ul style="list-style-type: none"> <li>• Participants: 22 (10 females, 12 males) with a high comorbidity burden and cognitive impairment.</li> <li>• Mean age of participants: 75 years.</li> <li>• Tools: Arch Height Index (AHI), Timed Up-and-Go (TUG), postural stability assessment, functional independence (Barthel Scale), cognitive function (Mini-Mental State Examination [MMSE]), depression assessment (Yesavage Scale), pressure ulcer risk (Norton Scale), balance and gait evaluation (Tinetti Scale), and fall risk assessment (Downton Scale).</li> <li>• Measures: Arch height, gait parameters, postural stability, independence in daily living, cognitive function, depression levels, pressure ulcer risk, balance, and fall risk.</li> </ul>	<ul style="list-style-type: none"> <li>• 3D-printed insoles with mechanical plantar stimulation improved several gait parameters.</li> <li>• 3D-printed insoles enhanced postural stability after one week.</li> <li>• The duration of the Timed Up-and-Go (TUG) test and step duration significantly decreased with 3D-printed insoles.</li> </ul>	3D-printed insoles with mechanical plantar stimulation improved gait and postural stability in older adults with cognitive impairment.
Wang et al. [50]	2020	Create 3D-printed insoles for patients with leg length discrepancy (LLD) to alleviate their symptoms	<ul style="list-style-type: none"> <li>• Participants: 7 (4 females, 3 males) with LLD of more than 5 mm, accompanied by lower back, hip, knee, or ankle pain.</li> <li>• Mean age of participants: 50 years.</li> <li>• Tools: Visual Analogue Scale (VAS) for pain evaluation, motion capture system, General Health Questionnaire-12 (GHQ-12), wooden blocks for measuring LLD.</li> <li>• Measures: LLD measurement, pain evaluation, gait parameters, and physical and mental conditions.</li> </ul>	<ul style="list-style-type: none"> <li>• Joint and lower back pain were alleviated.</li> <li>• Stride frequency, stride length, and pace improved in all seven cases.</li> <li>• Patients' overall GHQ-12 scores improved significantly.</li> </ul>	3D-printed insoles relieved muscle and joint pain in patients with LLD and improved their gait.
Malki et al. [51]	2024	Assess how 3D-printed rocker midsoles and self-adjusting insoles (SAI) affect dynamic stability in individuals with diabetic peripheral neuropathy (DPN) compared to healthy individuals.	<ul style="list-style-type: none"> <li>• Participants: 29 (16 males, 13 females).</li> <li>• Groups: Patients 19 (14 males, 8 females with DPN) and healthy participants 10 (2 males, 8 females).</li> <li>• Mean age of participants: <math>\geq 18</math> years</li> <li>• Tools: Motion Capture System and treadmill.</li> <li>• Measures: Margin of Stability (MoS) (anteroposterior (AP)/mediolateral (ML)) at heel strike, kinematic data for center of mass, and preferred walking speed.</li> </ul>	<ul style="list-style-type: none"> <li>• No significant difference in MOS-AP between the two groups.</li> <li>• DPN group, the SAI condition showed a significantly lower MOS-AP vs. the rocker condition.</li> <li>• The healthy group had a significantly lower MOS-ML than the DPN group, with no significant differences among DPN conditions.</li> <li>• The DPN group faced specific stability challenges under certain conditions.</li> </ul>	No difference in anteroposterior stability between healthy participants and those with DPN, but the DPN group had larger mediolateral stability. Experimental footwear did not affect this, suggesting it may help maintain stability in DPN patients.
Malki et al. [30]	2024	Assess the effectiveness of 3D-printed rocker and self-adjusting insole (SAI) in reducing peak pressure for individuals with diabetes and loss of protective sensation.	<ul style="list-style-type: none"> <li>• Participants: 21 (16 males, 5 females) with diabetes with Loss of Protective Sensation.</li> <li>• Mean age of participants: <math>\geq 18</math> years</li> <li>• Test conditions: Control (Control shoe with control insole), self-adjusting insole (SAI) (Control shoe with SAI), rocker (Rocker shoe with control insole), and Rocker-SAI (Rocker shoe with SAI).</li> <li>• Tools: Plantar pressure measurement system, treadmill, motion capture system, Timed Up &amp; Go (TUG) Test, Romberg Test, and Biothesiometer.</li> <li>• Measures: Peak pressure (PP) in specific foot regions, balance, the time taken to rise from a chair, walk 3 m, turn, and return to the chair.</li> </ul>	<ul style="list-style-type: none"> <li>• The combination of 3D-printed rocker midsoles and self-adjusting insoles effectively reduced peak plantar pressure (PP) in all feet, with the toes, central, and lateral forefoot areas identified as regions at risk.</li> <li>• For the medial forefoot, PP was successfully reduced in most feet.</li> <li>• No intervention achieved successful PP reduction in all feet with the heel identified as a region at risk.</li> </ul>	3D-printed rocker midsoles and self-adjusting insoles effectively reduce peak plantar pressure in the forefoot but not in the heels. To enhance results, insoles with arch support, heel cups, and flexible midsoles are recommended.

were included only if there was sufficient consistency in clinical outcomes across studies, with a specific focus on evaluating the gait parameters (plantar pressure, kinetics, and kinematics), functional performance (Activities of Daily Living (ADLs) and grip strength), radiographic

measurements, comfort, fit, and overall effectiveness of 3D-printed orthoses. Clinical outcomes were grouped by orthotic type, including insoles, AFOs, spinal orthoses, upper-limb orthoses, and helmets. Subgroup analyses were conducted separately for each 3D-printed orthosis

based on the type and/or clinical outcomes. Data were extracted by one reviewer (T.Q) and cross-checked for accuracy by a second reviewer (H.A). Discrepancies were resolved through discussion. Data management was conducted using Excel and Word.

### Methodological quality assessment

Quality assessment of the selected articles was conducted by two authors, (H.R.B and H.A). A third author (G.F) made the final decision in instances where a decision could not be reached. Each study was assessed individually using the modified Downs & Black Checklist [22]. This checklist was chosen due to its validity as a tool for evaluating the methodological quality of randomized and non-randomized controlled trials, and it has been recognized as a high-ranking quality assessment instrument for systematic reviews. The checklist consists of 27 items divided into five categories: study quality, external validity, internal validity bias, confounding selection bias, and study power, with a maximum score of 28 points. Each item is scored with one point, except for item 27, which is worth two points. Score ranges were assigned to reflect corresponding quality levels as previously established: excellent (26-28); good (20-25); fair (15-19); and poor (<14).

### Results

A PRISMA flowchart of the study identification process is presented in Fig. 1. Of the 1279 potential records, 856 studies underwent title/abstract screening, 141 were reviewed in full, and 62 studies were ultimately included for appraisal.

The search resulted in 13 cross-sectional studies, 25 randomized controlled trials (including crossover trials), and 24 studies employing other designs (such as prospective/retrospective cohort, within-subjects, case series, pilot/feasibility, descriptive/observational, and quasi-experimental studies). Complete details of the study characteristics are summarised in the *Supplementary Table 2*. Studies represented data from 3,815 participants. Across studies, participants represented a variety of medical condition and indication for orthosis. Studies reported the use of 3D-printing insoles [6, 9, 10, 13, 23–51] (Table 1), AFOs [52–54] (Table 2), spinal orthoses [14, 55–58] (Table 3), upper-limb orthoses [8, 11, 12, 59–72] (Table 4), and helmets [73, 74] (Table 5). Selected studies were matched with the clinical outcomes as shown in the *Supplementary Table 3*.

Across the 62 included studies, consistent patterns were observed in favor of 3D-printed orthoses. The most prominent clinical benefits included enhanced gait parameters, effective plantar pressure redistribution, improved grip strength, and greater patient satisfaction. While studies on insoles and AFOs frequently

demonstrated biomechanical improvements (e.g., increased dorsiflexion and decreased peak pressures), upper-limb orthoses improved functional performance in activities of daily living. Spinal orthoses consistently reduced Cobb angles in scoliosis, and helmet orthoses improved cranial symmetry. Notably, many studies reported better comfort, fit, and reduced production time compared to conventional methods. Although heterogeneity in study designs precluded meta-analysis, the narrative synthesis underscores the practical clinical promise of 3D-printed orthoses across domains.

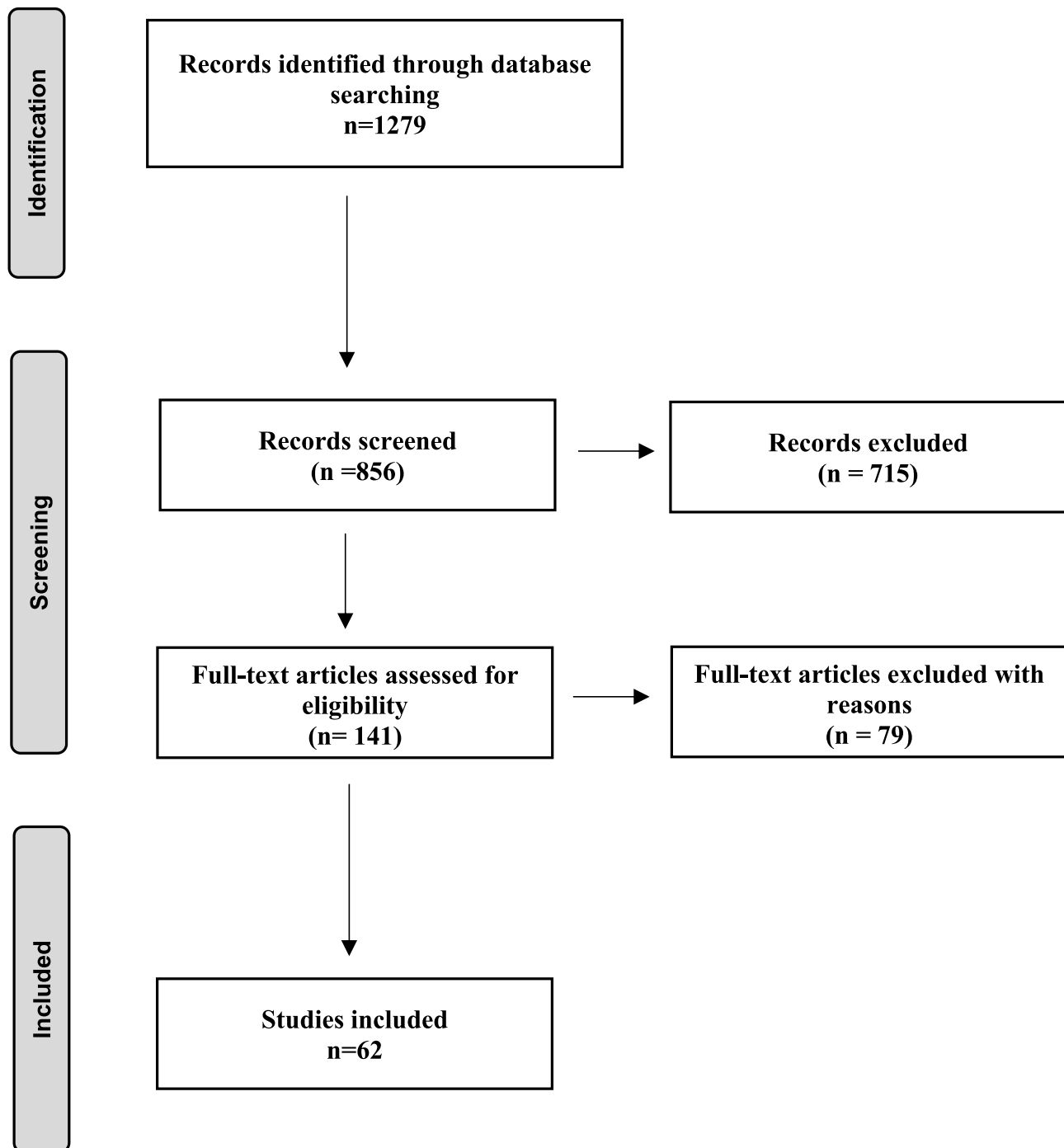
In terms of methodological quality, the Modified Downs & Black checklist ratings of included studies are summarised in *Supplementary Table 4*. One study was rated poor, 25 studies were rated fair, and 36 were rated good. Common limitations among fair-quality studies included unclear blinding procedures, small sample sizes, and lack of power analysis. Overall, most included studies demonstrated moderate to high methodological rigor, supporting the reliability of the reported clinical outcomes.

### Discussion

This review examines the clinical outcomes of 3D-printed orthoses, including insoles, AFOs, spinal orthoses, upper-limb orthoses, and helmets, focusing on clinical outcomes, as gait parameters, functional performance, radiographic measurements, comfort, fit, and effectiveness.

The reviewed studies included participants with diverse characteristics, including stroke survivors, individuals with cerebral palsy (CP), spinal cord injury (SCI), scoliosis, and musculoskeletal disorders. Notably, orthosis outcomes varied based on age and disease severity. For instance, Aihara et al. [74] found that in cranial deformities, the degree of deformity had a greater impact than age on helmet effectiveness, with longer therapy durations yielding improved outcomes. Similarly, Ragni et al. [68] and Madaan et al. [69] noted that children with severe spasticity from CP benefited significantly from dynamic upper limb orthoses when combined with occupational therapy. This suggests a need for stratified analysis based on patient profiles in future studies.

Furthermore, functional movement improvements varied by orthosis type. For instance, upper-limb orthoses enhanced fine motor tasks such as eating and brushing in individuals with SCI and stroke, while AFOs primarily improved gross motor tasks like walking symmetry and weight distribution in post-stroke and hemiplegic patients. These comparisons highlight the specificity of orthotic interventions across motor domains, which is often underreported in the literature.



**Fig. 1** PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart

### 3D-printed insoles

Most studies on 3D-printed insoles used plantar pressure measurement [6, 32, 34, 41], motion capture [6, 25, 33, 34, 36, 38, 39, 41, 42, 51], force plate [33, 40, 42], electromyography [44], skin temperature and humidity sensors [31], and other rehabilitation outcome measures to assess variables such as comfort [10, 31–33, 35, 46, 48–50]. The studies compared 3D-printed insoles based on different

designs [30, 33, 34, 38, 43, 75], stiffness levels [10, 13, 28, 32, 34, 38, 41, 51], and hybrid insoles [24], as well as other types, including prefabricated and traditionally made insoles [6, 9, 10, 26, 27, 36, 47].

Research on 3D-printed insoles primarily focused on plantar pressure [9, 13, 23, 24, 26–29, 51, 75]. Findings indicate that 3D-printed insoles can effectively reduce plantar pressure by improving pressure distribution,

**Table 2** 3D-printed ankle foot orthoses

Author	Year	Aim	Methods	Results	conclusion
Rohit et al. [52]	2023	Investigate the effects on patients with drop foot	<ul style="list-style-type: none"> <li>Participants: 3 participants with unilateral drop foot. (Genders were not specified).</li> <li>Mean age of participants: Not provided</li> <li>Tools: Motion Capture Systems, Force Plates, Questionnaires, Vernier Calipers and Goniometers, Weight scale</li> <li>Measures: Gait (velocity, stride length, and stability), and anthropometric assessments (fit) and questionnaires (patient feedback on comfort and usability).</li> </ul>	Gait dynamics: <ul style="list-style-type: none"> <li>Increased ankle dorsiflexion</li> <li>Enhanced ankle power</li> <li>Boosted walking velocity</li> <li>improved ankle motion (+81.27%), and power (+36.84% to +60.57%)</li> <li>knee flexion improvement (+23.39% to +36.75%) and minimal hip improvement.</li> </ul>	3D-printed AFO struts can improve gait for patients with drop foot.
Harper et al. [53]	2014	The effect of strut stiffness level in 3D-printed Passive-dynamic AFOs on walking performance.	<ul style="list-style-type: none"> <li>Participants: 13 male participants with unilateral lower-limb impairments.</li> <li>Mean age of participants: 29 years</li> <li>Tools: Force plates, Motion capture system, and electromyogram (EMG).</li> <li>Measures: Joint angles, moments, work, ground reaction forces, and muscle activities.</li> <li>Three types of passive-dynamic ankle-foot orthoses comparison:               <ol style="list-style-type: none"> <li>Clinically prescribed carbon fiber orthosis (baseline).</li> <li>20% more compliant than the baseline.</li> <li>20% more stiff than the baseline.</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>Different stiffness levels had minimal impact on gait kinematics and kinetics.</li> <li>Notable effects on knee flexion, plantarflexion, medial ground reaction force impulses, and negative knee work in stiffer AFOs.</li> <li>EMG showed slight increases in medial gastrocnemius activity in the compliant AFO.</li> </ul>	Stiffness of the 3D-printed AFO doesn't greatly affect walking performance, but may influence balance.
Fu et al. [54]	2022	Compare between 3D-printed hinged AFO and anterior AFO on plantar parameters.	<ul style="list-style-type: none"> <li>Participants: 10 (2 females, 8 males) All participants had experienced a first ever unilateral hemiplegic stroke at least 3 months before the data was collected. Their functional ambulation was rated at a category 3 or higher, and their lower extremity motor recovery was at Brunnstrom stage III-IV.</li> <li>Mean age of participants: 54 years.</li> <li>Tools: Plantar Pressure Measurement System, Quebec User Evaluation of Satisfaction with Assistive Technology questionnaire.</li> <li>Measures: Plantar parameters (contact area, force, peak pressure), gait symmetry, and satisfaction while walking with 3DP-HAFO, anterior AFO, and barefoot.</li> </ul>	<ul style="list-style-type: none"> <li>Increased medial midfoot peak pressure and contact area with the 3DP-HAFO compared to barefoot walking.</li> <li>3DP-HAFO improved weight distribution symmetry between the affected and unaffected legs compared to barefoot and anterior AFO.</li> <li>3DP-HAFO corrected equinovarus deformity more effectively than anterior AFO, providing better medial-lateral ankle control.</li> <li>Enhanced patient satisfaction with the 3DP-HAFO compared to anterior AFO in terms of fitting and durability.</li> <li>No significant differences in gait speed or cadence between 3DP-AFO and anterior AFO.</li> </ul>	The 3DP-HAFO can increase the medial midfoot pressure, promote more symmetrical gait, and medial weight-bearing.

particularly in the heel and metatarsal regions [23, 24, 26, 27, 29, 75]. Additionally, they have been shown to improve efficiency [13], enhance design and outcomes [13], provide a cost-effective alternative to traditional methods [13], offer greater durability, allow for targeted adjustments based on pressure data and patient-specific modelling [24], enhance comfort [9, 27], aid in injury prevention, and lower the risk of ulcerations [29].

Other research has evaluated the comfort of users wearing 3D-printed insoles [10, 31, 32]. These studies reported that 3D-printed insoles improve overall comfort, provide better heel cushioning, and offer superior arch support compared to prefabricated insoles [10, 32]. In contrast, Ning et al. [31] found that textile insoles provide better moisture management and comfort than other types, including 3D-printed insoles [31]. Additionally, all insole types showed no significant differences in skin temperature [31]. Channasanon et al. [32] also

concluded that material hardness does not affect plantar pressure distribution.

Studies have also applied 3D-printed insoles for individuals with flat feet [33–37]. These studies found that 3D-printed insoles can effectively aid in treating flat feet by improving arch support, controlling hindfoot eversion and forefoot abduction [33–36], increasing ankle dorsiflexion [33, 34], enhancing comfort [33], offloading the hindfoot [34], improving muscle strength and endurance [37], dynamic balance [37], could offer a cost-effective alternative for custom foot orthotic manufacturing. Hsu et al. [33] concluded that 3D-printed wedge insole produced the best results for ankle joint deformity correction.

Eight studies investigated the effects of 3D-printed insoles with wedges on realigning lower-limb joints [25, 38–44]. Desmyttere et al. [38], Jin et al. [25], and Lin et al. [40] reported that 3D-printed insoles with a lateral

**Table 3** 3D-printed spinal orthoses

Author	Year	Aim	Measures	Results	Conclusion
Jin et al. [55]	2022	Evaluate the effectiveness of a 3D-printed spinal orthosis, combined with Traditional manipulative physiotherapy, for managing adult new-onset scoliosis	<ul style="list-style-type: none"> <li>• Participants: 9 (8 females, 1 male) adults with new-onset scoliosis with Cobb angle between 10° and 40°.</li> <li>• Mean age of participants: 31 years.</li> <li>• Tools: Visual Analog Scale (VAS), Functional Movement Screen (FMS), Activities of Daily Living (ADL) Scale.</li> <li>• Measures: Cobb angle, pain levels, motor function, and daily activity performance before and after treatment.</li> </ul>	<ul style="list-style-type: none"> <li>• The 3D-printed spinal orthosis led to significant improvements in all patients after treatment, including a decrease in Cobb angle, compared to the thermoplastic spinal orthosis.</li> <li>• The 3D-printed spinal orthosis reduced lower back pain levels and increased motor function compared to the thermoplastic spinal orthosis.</li> <li>• The 3D-printed spinal orthosis showed some improvement in activities of daily living (ADL) scores.</li> <li>• The 3D-printed spinal orthosis achieved a full effective rate based on improvement criteria for spinal curvature and functional outcomes.</li> </ul>	The 3D-printed spinal orthosis would effectively treat scoliosis, enabling precise spinal correction and improvements in alignment and pain relief.
Li et al. [56]	2024	Evaluate the effectiveness, safety, and benefits of a 3D-printed spinal orthosis for treating adolescent idiopathic scoliosis (AIS)	<ul style="list-style-type: none"> <li>• Participants: 103 (19 males, 84 females) with Adolescent Idiopathic Scoliosis (AIS) with a Cobb angle between 10° and 40°.</li> <li>• Groups: Experimental (55 patients (7 males, 48 females) fitted with a 3D-printed spinal orthosis) and control (48 patients (12 males, 36 females) fitted with a thermoplastic spinal orthosis).</li> <li>• Mean age of participants: 12 years.</li> <li>• Tools: Radiographic measurements, health-related quality of life (HRQoL) questionnaires, compliance assessment.</li> <li>• Measures: Cobb angle, Nash grade, thoracic kyphosis angle, lumbar lordosis angle, quality of life, overall health, and brace-wearing habits.</li> </ul>	<ul style="list-style-type: none"> <li>• The experimental group showed significantly lower Cobb angles, Nash grades, and improved HRQoL scores compared to the control group.</li> <li>• Only one patient in the experimental group experienced major curved progression, compared to 10 patients in the control group.</li> <li>• Fewer surgeries were required in the experimental group compared to the control group.</li> </ul>	The 3D-printed spinal orthosis significantly reduces Cobb curve progression and improves quality of life in AIS patients compared to the thermoplastic spinal orthosis, highlighting its efficacy, safety, and potential to improve treatment outcomes.
Lin et al. [57]	2022	Compare the clinical effectiveness and quality of life (QoL) outcomes between 3D-printed spinal orthosis and thermoplastic spinal orthosis.	<ul style="list-style-type: none"> <li>• Participants: 22 females (initially 30) with Adolescent Idiopathic Scoliosis (AIS) and a Cobb angle between 20° and 40°.</li> <li>• Groups: Experimental (15 patients fitted with a 3D-printed spinal orthosis) and control (15 patients fitted with a thermoplastic spinal orthosis).</li> <li>• Mean age of participants: 12 years</li> <li>• Tools: Cobb angle measurement, three validated questionnaires, and thermosensors.</li> <li>• Measures: Cobb angle, quality of life (QoL), compliance, curve progression, and daily wearing hours.</li> </ul>	<ul style="list-style-type: none"> <li>• Both 3D-printed and thermoplastic spinal orthoses significantly reduced the Cobb angle.</li> <li>• QoL scores declined in both groups, with no significant differences between them.</li> <li>• After 2 years, angle reduction was observed in both groups.</li> <li>• Average daily hours were similar in both groups.</li> </ul>	The 3D-printed spinal orthosis provided clinical effects comparable to those of the thermoplastic spinal orthosis, with similar compliance and quality of life outcomes for patients.
Lou et al. [58]	2022	Compare the effectiveness and efficiency of 3D-printed spinal orthosis versus thermoplastic spinal orthosis in treating scoliosis.	<ul style="list-style-type: none"> <li>• Participants: 6 (5 females, 1 male) with Adolescent Idiopathic Scoliosis (AIS) and a pre brace Cobb angle between 20° and 45°.</li> <li>• Mean age of participants: 12 years.</li> <li>• Tools: Radiography system, Brace Risser Sign Index (BRSI), measurement software, cost analysis framework, and standard measurement instruments.</li> <li>• Measures: Radiographic correction (pre- and in-brace Cobb angles and percentage correction), spinal flexibility, casting and manufacturing time, physical characteristics, and cost analysis.</li> </ul>	<ul style="list-style-type: none"> <li>• The Cobb angle decreased after 6 weeks of wearing the 3D-printed spinal orthosis.</li> <li>• The thermoplastic spinal orthosis required more hours of labor compared to the 3D-printed orthosis.</li> <li>• The thermoplastic spinal orthosis was thicker than the 3D-printed version.</li> <li>• The thermoplastic spinal orthosis cost more than the 3D-printed spinal orthosis, highlighting effective correction and labor savings.</li> </ul>	The 3D-printed spinal orthosis is as effective as the thermoplastic spinal orthosis, but is thinner, lighter, cheaper, and requires fewer manufacturing hours, making it a viable alternative for scoliosis treatment.

**Table 3** (continued)

Author	Year	Aim	Measures	Results	Conclusion
Storm et al. [14]	2022	Evaluate a spinal orthosis production process using deposition modeling (3D-printed spinal orthosis) for treating patients with scoliosis and osteogenesis imperfecta, and compare postural stability metrics	<ul style="list-style-type: none"> <li>• Participants: 10 (8 females, 2 males) 8 participants had Idiopathic scoliosis and 2 osteogenesis imperfecta).</li> <li>• Groups: Unbraced and 3D-printed and thermo-plastic spinal orthoses.</li> <li>• Mean age of participants: AIS patients (15), OI (8) years.</li> <li>• Tools: Wireless wearable device with a tri-axial accelerometer, Production evaluation criteria (3D chest acquisition attempts, CAD design time, Additive manufacturing attempts, and post-processing time)</li> <li>• Measures: Postural stability metrics, brace compliance, and production process evaluations.</li> <li>• Methods: Patients were tested in both unbraced and 3D-printed spinal orthosis conditions. After 2 weeks, patients switched back to their thermo-plastic spinal orthosis.</li> </ul>	<ul style="list-style-type: none"> <li>• Out of ten cases, seven scans were optimal, two good, and one acceptable due to patient movement.</li> <li>• CAD design took 40 min to 2 h, with most cases rated good or acceptable, and post-processing took 40 min to 1 h 40 min, with six cases rated good and four acceptable.</li> <li>• Most of the 3D-printed spinal orthoses were printed successfully on the first attempt, with two minor adverse events noted.</li> <li>• The 3D-printed spinal orthosis had lower anterior-posterior acceleration compared to unbraced conditions</li> <li>• The thermoplastic spinal orthosis showed reduction in sway path length compared to unbraced.</li> <li>• No significant differences were found between the two spinal orthosis types.</li> </ul>	3D-printed spinal orthoses are viable alternatives to thermoplastic type, offering similar postural stability. Challenges in additive manufacturing can be addressed, with potential for improved efficiency and reduced material waste.

heel wedge reduced ankle joint inversion and knee joint adduction moments. As a result, they could be considered a conservative treatment for individuals with medial knee joint osteoarthritis. In contrast, Mannisi et al. [39] found no significant reduction in the knee adduction moment. Desmyttere et al. [41] and Telfer et al. [42] observed that 3D-printed insoles with a medial heel wedge decreased rear-foot eversion but worsened medial knee joint osteoarthritis due to an increased knee joint abduction moment. Zhang and Vanwanseele [43] reported that 3D-printed insoles with a medial forefoot wedge reduced the forefoot abduction moment, making them beneficial as an anti-pronator component. Additionally, Telfer et al. [44] found that 3D-printed insoles with either a lateral or medial heel wedge influenced plantar pressure distribution and muscle activity. Desmyttere et al. [38] also reported that a 3D-printed insole with a heel raise shifted the load from the rear-foot to the mid-foot.

Two studies examined 3D-printed insoles for treating foot-related musculoskeletal alignment issues. Shaikh et al. [45] found that treating 200 individuals with flat feet using 3D-printed insoles alleviated joint pain while enhancing comfort and functionality. Lastly, Tarrade et al. [46] reported that 3D-printed insoles helped relieve foot pain in workers who stand for extended periods.

Salles and Gyi [6] and Mo et al. [47] evaluate the effects of 3D-printed insoles on runners' performance. Salles and Gyi [6] found that 3D-printed insoles with a heel cup and rigid arch support improved fit, reduced heel discomfort, and decreased ankle joint dorsiflexion and heel pressure. Mo et al. [47] reported that both 3D-printed and prefabricated insoles improved comfort and reduced peak rear-foot eversion while running. Still,

they found no significant differences in vertical loading rates between the two. However, 3D-printed insoles can still be considered a viable alternative for clinical use [47].

Brogna et al. [48] and Brogna et al. [49] evaluated the effects of 3D-printed insoles on stability. They reported that the 3D-printed insoles improved gait stability and symmetry and increased stride length in patients with Parkinson's disease compared to those with other neurological disorders [48]. Moreover, improved gait and postural stability for older adults [49]. Wang et al. [50] concluded that 3D-printed insoles relieved muscle and joint pain in patients with leg length discrepancy and improved their gait.

Malki et al. [30, 51, 76] evaluated the effectiveness of 3D-printed rockers and self-adjusting insoles in individuals with diabetic peripheral neuropathy. Their findings showed that diabetic patients exhibited increased medio-lateral stability [51], the insoles reduced peak plantar pressure under the forefoot but not under the heels [30], while further reduction in proximal heel pressure may be achievable with more flexible midsole materials [76]. there was no significant difference in anteroposterior stability compared to healthy participants [51], and insoles with arch support, heel cups, and flexible midsoles are recommended [30].

We noticed that the studies collectively highlighted the advantages of 3D-printed insoles, especially in improving pressure distribution, comfort, fit, and overall alignment. On the other hand, variations in material stiffness and wedge positioning contributed to mixed findings regarding their impact on proximal joints. A few studies showcased outstanding results in pain relief and gait stability, while others suggested minimal differences compared to prefabricated devices. The effectiveness of 3D-printed

**Table 4** 3D-printed upper-limb orthoses

Author	Year	Aim	Methods	Results	Conclusion
Graham et al. [11]	2020	Determine the effectiveness of immobilization in 3D-printed wrist splints compared to fiberglass wrist splints.	<ul style="list-style-type: none"> <li>Participants: 12 healthy participants (7 females, 5 males)</li> <li>Mean age of participants: 38 years</li> <li>Tools: The Jebsen Hand Function Test (JHFT) and Patient-Rated Wrist Evaluation (PRWE).</li> <li>Measures: Ability to complete seven distinct subtests related to everyday unilateral hand use (dominant and non-dominant hand), function and pain scales, differences in task performance, and functional questionnaire results.</li> <li>Methods: Participants were fitted with both 3D-printed and fiberglass wrist splints in separate sessions.</li> </ul>	<ul style="list-style-type: none"> <li>No significant differences were observed in the JHFT between 3D-printed and fiberglass wrist splints. However, one-third of participants fitted with the 3D-printed splint were able to complete tasks within a normal time, which they could not achieve with the fiberglass splint.</li> <li>The average PRWE function score was lower in patients using 3D-printed splints compared to those using fiberglass wrist splints.</li> <li>Minor skin irritation was reported by nearly half of the patients fitted with fiberglass wrist splints, whereas only one patient experienced irritation with the 3D-printed splint.</li> <li>One patient with a fiberglass wrist splint required a cast change due to an improper fit.</li> </ul>	Both 3D-printed and fiberglass wrist splints demonstrate similar objective function. However, patient satisfaction, comfort, and perceived function are superior with 3D-printed wrist splints compared to fiberglass wrist splints.
Guebali et al. [59]	2024	To compare the effectiveness and patient satisfaction of 3D-printed wrist splints versus fiberglass wrist splints in treating non- or minimally displaced distal radial fractures.	<ul style="list-style-type: none"> <li>Participants: 39 (16 males, 23 females) with non-displaced or minimally displaced distal radius fractures.</li> <li>Groups: Group A (20 patients (8 males, 12 females) fitted with fiberglass wrist splints) and Group B (19 patients (8 males, 11 females) fitted with 3D-printed wrist splints).</li> <li>Mean age of participants: Group A (48), Group B (41).</li> <li>Tools: Modified Patient Satisfaction Questionnaire, Modified Clinical Effectiveness Assessment, Visual Analogue Scale (VAS), goniometer, dynamometer, Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire, and Patient-Rated Wrist Evaluation (PRWE) Score</li> <li>Measures: Clinical effectiveness, patient satisfaction, pain levels, range of motion, and grip strength</li> </ul>	<ul style="list-style-type: none"> <li>At 6 weeks, Group B had a higher patient satisfaction score compared to Group A.</li> <li>Clinical effectiveness scores were similar between Groups A and B.</li> <li>No significant differences were found between Groups A and B in pain levels, range of motion, or grip strength.</li> <li>Group B experienced more complications than Group A.</li> </ul>	3D-printed wrist splints are a good alternative to fiberglass splints for distal radial fractures, offering greater patient satisfaction and effectiveness, though they come with higher costs, longer production times, and the potential for minor complications.
Xiao et al. [12]	2024	Test the clinical feasibility and safety of 3D-printed wrist splints compared to thermoplastic wrist splints for immobilizing Colles' fractures.	<ul style="list-style-type: none"> <li>Participants: 40 (16 males, 24 females) with Colles' fracture.</li> <li>Groups: Observation group (20 patients (7 males, 13 females) fitted with 3D-printed wrist splints) and control group (20 patients (9 males, 11 females) fitted with thermoplastic wrist splints).</li> <li>Mean age of participants: Observation group (45), Control group (44) years.</li> <li>Tools: Visual Analogue Scale (VAS), Immobilization Scoring, Satisfaction Questionnaire, and Disability of the Arm, Shoulder, and Hand (DASH) score.</li> <li>Measures: Wrist pain, immobilization effectiveness, patient satisfaction, and function. Complications such as skin irritation and fracture displacement were also recorded.</li> </ul>	<ul style="list-style-type: none"> <li>At 2 and 6 weeks, VAS scores decreased in both groups, with the observation group showing greater improvement at 2 weeks.</li> <li>Immobilization and satisfaction scores were higher in the observation group at 6 weeks, while DASH scores were lower at both 2 and 6 weeks.</li> <li>No cast breakages were reported, but two cases of skin irritation occurred in the control group.</li> <li>Radiographs showed improved palmar tilt and ulnar inclination in the observation group at both 2 and 12 weeks.</li> </ul>	Both 3D-printed and thermoplastic wrist splints are effective for treating Colles' fractures, but 3D-printed wrist splints provide better clinical performance, imaging outcomes, and patient satisfaction.

**Table 4** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Skibicki et al. [8]	2021	Compare the radiographic outcomes and patient satisfaction for fractures treated with 3D-printed wrist splints versus fiberglass wrist splints.	<ul style="list-style-type: none"> <li>• Participants: 22 patients with 23 limbs treated (15 males, 7 females).</li> <li>• Groups: Group A (10 patients (8 males, 2 females) fitted with 3D-printed wrist splints) and Group B (12 patients (7 males, 5 females) fitted with fiberglass wrist splints).</li> <li>• Mean age of participants: 11 years</li> <li>• Tools: Radiographic analysis, Visual Analog Scale (VAS), blinded hand therapist evaluation, orthotist evaluation.</li> <li>• Measures: X-ray alignment and healing, fit, skin appearance, ease of care, and overall satisfaction.</li> </ul>	<ul style="list-style-type: none"> <li>• About 90% of patients in both groups healed in an excellent position, with one patient in each group healing in an acceptable position.</li> <li>• No differences in skin irritation were observed between the two groups, as assessed by a blinded hand therapist.</li> <li>• Patients reported significant differences in skin irritation, comfort, satisfaction, and ease of care, with 3D-printed wrist splints being favored over fiberglass wrist splints.</li> </ul>	3D-printed splints offer a promising opportunity to enhance patients' experiences with upper extremity casting while ensuring proper immobilization.
Oud et al. [60]	2023	To assess the effectiveness of 3D-printed versus conventional wrist splints in individuals with chronic hand conditions.	<ul style="list-style-type: none"> <li>• Participants: 20 participants with a variety of chronic hand conditions resulting from neuromuscular diseases, neurological disorders, musculoskeletal disorders, or injuries. (Genders were not specified)</li> <li>• Mean age of participants: ≥18 years.</li> <li>• Tools: Visual Analog Scale (VAS), Michigan Hand Outcomes Questionnaire (MHQ), EuroQoL 5-Dimension 5-Level (EQ-5D-5 L).</li> <li>• Measures: Pain reduction, hand function, and quality of life.</li> <li>• Methods: The 3D-printed hand splints (intervention) were compared to the participants' currently used conventional hand splints (baseline control).</li> </ul>	<ul style="list-style-type: none"> <li>• Participants reported a significant reduction in pain while using 3D-printed versus conventional hand splints.</li> <li>• 3D-printed hand splints showed a notable improvement in hand function and enhanced the ability to perform daily activities compared to conventional splints.</li> <li>• Quality of life improved significantly, reflecting better overall well-being and less impact from the participants' hand conditions with 3D-printed splints compared to conventional ones.</li> </ul>	3D-printed hand splints can reduce pain, improve hand function, and enhance quality of life, supporting their use in managing chronic hand conditions.
Oud et al. [61]	2024	Compare 3D-printed and conventional wrist splints in terms of function, satisfaction, quality of life, and production time/costs in individuals with chronic hand conditions	<ul style="list-style-type: none"> <li>• Participants: 21 individuals (5 males, 16 females) with chronic hand conditions, with 19 completing the follow-up assessments</li> <li>• Groups: Experimental group (3D-printed hand splints) and control group (conventional hand splints).</li> <li>• Mean age of participants: 61 years.</li> <li>• Tools: Dutch-Flemish PROMIS Upper Extremity (DF-PROMIS-UE), Michigan Hand Questionnaire, EuroQoL 5-Dimension 5-Level (EQ-5D-5 L), Visual Analogue Scale (VAS), Client Satisfaction with Device (CSD), Quebec User Evaluation of Satisfaction with Assistive Technology (D-QUEST), production time and cost records.</li> <li>• Measures: Performance of activities of daily living (ADLs), general hand function, quality of life, orthosis satisfaction, production time and costs, adverse events.</li> </ul>	<ul style="list-style-type: none"> <li>• No significant differences in ADL performance or quality of life were found between 3D-printed and conventional hand splints at 1 and 4 months.</li> <li>• 3D-printed hand splints received higher satisfaction ratings due to their better fit and lighter weight compared to conventional splints.</li> <li>• 3D-printed hand splints had lower production time and costs but were associated with some mild adverse events compared to conventional splints.</li> <li>• While functionality was similar, 3D-printed hand splints provided greater satisfaction and cost efficiency than conventional splints.</li> </ul>	3D-printed hand splints match conventional ones in function and quality of life, while offering added comfort and lower costs.

**Table 4** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Zheng et al. [62]	2020	Compare the effects of 3D-printed and thermoplastic wrist splints in chronic hemiparetic stroke patients.	<ul style="list-style-type: none"> <li>• Participants: 40 patients (31 males, 9 females) with chronic hemiparetic stroke.</li> <li>• Groups: Experimental group 20 participants, 15 males, 5 females (3D-printed hand splints) and control group 20 participants, 16 males, 4 females (thermoplastic hand splints).</li> <li>• Mean age of participants: Experimental group (55), Control group B (60) years.</li> <li>• Tools: Modified Ashworth Scale, manual goniometer, Fugl-Meyer Assessment, visual analogue scale, four-point swelling score, and the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST).</li> <li>• Measures: Spasticity, range of motion (RoM), motor function, pain intensity, swelling score, and patient satisfaction.</li> <li>• Methods: All measures were evaluated at baseline and six weeks, with spasticity also assessed at three weeks.</li> </ul>	<ul style="list-style-type: none"> <li>• The experimental group showed greater spasticity relief, improved passive range of motion (RoM) and ulnar deviation, and a reduction in swelling compared to the control group.</li> <li>• No significant differences were found in pain or subjective feeling scores between the two groups.</li> </ul>	3D-printed hand splints effectively reduce spasticity and swelling while improving wrist function, offering better personalization and support as a rehabilitation tool.
Kim et al. [63]	2018	To develop a 3D-printed wrist splint and assess its impact on pain relief, work performance, and daily life satisfaction in patients with overuse syndrome.	<ul style="list-style-type: none"> <li>• Participants: 20 initially 22 (15 males, 5 females) (with wrist pain from overuse syndrome).</li> <li>• Groups: Control group 10 participants (7 males, 3 females) fitted with ready-made wrist supports, and experimental group 10 participants (8 males, 2 females) fitted with 3D-printed wrist supports.</li> <li>• Mean age of participants: Control group (31), experimental group (33) years.</li> <li>• Tools: Patient-Rated Wrist Evaluation (PRWE), Jebsen Hand Function Test (JHFT), and Orthotics and Prosthetics Users' Survey (OPUS).</li> <li>• Measures: Pain relief, hand functionality, and overall satisfaction with the orthosis.</li> </ul>	<ul style="list-style-type: none"> <li>• After 1 week, the experimental group reported a greater reduction in pain compared to the control group.</li> <li>• Hand function improved similarly in both groups.</li> <li>• The 3D-printed wrist splints were worn significantly more than the ready-made ones.</li> <li>• Satisfaction was higher for specific tasks in the experimental group, such as brushing teeth and dialing a phone, compared to the control group.</li> </ul>	The 3D-printed wrist splints provided similar pain relief and functionality to ready-made ones, while offering superior user satisfaction, making them a viable alternative.
Portnoy et al. [64]	2020	To develop software for 3D-printed finger splints for swan-neck deformity and compare it to the conventional method in terms of preparation time, weight, and user satisfaction among Occupational Therapy (OT) students	<ul style="list-style-type: none"> <li>• Participants: 36 female healthy Occupational Therapy (OT) students.</li> <li>• Mean age of participants: 25 years</li> <li>• Tools: Quebec User Evaluation of Satisfaction with Assistive Technology 2.0 (QUEST 2.0) scale, weighing device, timer, rubber hand mannequin, and calliper.</li> <li>• Measures: User satisfaction (fit, aesthetics, difficulty of preparation, and overall preparation process), preparation time, splint weight, and preference for method (3D-printed vs. conventional).</li> </ul>	<ul style="list-style-type: none"> <li>• OT students preferred the 3D-printed method over the conventional one for preparing finger splints and reported higher satisfaction with its fit, aesthetics, and overall process.</li> <li>• The 3D-printed finger splints were lighter but required more preparation time compared to those made using the conventional method.</li> <li>• Preferences varied, with 44.4% favoring 3D-printed finger splints for swan-neck deformity and 66.7% for more complex splints.</li> </ul>	Utilizing 3D-printed software for fabricating finger splints can streamline clinic workflows by enhancing 3D-printing integration and improving customization, efficiency, fit, and aesthetics for both simple and complex finger deformities.

**Table 4** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Huber et al. [65]	2023	Evaluate a 3D-printed dynamic hand orthosis with finger-extension assist by comparing it to a commercial version and assessing the impact of 3D-printed materials on hand function.	<ul style="list-style-type: none"> <li>Participants: 5 male stroke survivors (Subacute or chronic stroke with moderate hand impairment).</li> <li>Mean age of participants: 50 years.</li> <li>Tools: Pincer Force Test, Pincer Aperture Test, Box and Block Test (BBT), usability survey (based on the Technology Acceptance Model).</li> <li>Measures: Hand biomechanics and upper extremity function without an orthosis, with different prototypes, and with the commercial version; intention to use, ease of use, intuitiveness, comfort, and aesthetics.</li> <li>Methods: The finger-extension component was replicated to create five prototypes, each with identical geometry but varying 3D-printing material compositions. The selected materials represented a range of elastic moduli, from low to relatively high stiffness.</li> </ul>	<ul style="list-style-type: none"> <li>No significant usability differences were found between the 3D-printed prototype and commercial orthoses.</li> <li>Three of the 3D-printed prototypes exhibited reduced pincer force, with increased stiffness further decreasing force.</li> <li>Higher elasticity (stiffness) resulted in a decrease in pincer force.</li> <li>The Box and Block Test revealed significant negative effects for both the 3D-printed and commercial dynamic hand orthoses compared to no brace, with stiffness impacting scores.</li> </ul>	3D-printed dynamic hand orthoses are feasible for stroke survivors, offering usability similar to that of commercial orthoses, with potential benefits in customization and stiffness.
Yang et al. [66]	2021	Evaluate the effects of a 3D-printed dynamic hand orthosis on hand motor function and spasticity in chronic hemiparetic stroke survivors and assess users' self-reported experiences and comfort with the splint.	<ul style="list-style-type: none"> <li>Participants: 25 participants (initially 30) (21 males, 4 females) chronic stroke patients with upper-limb spasticity (Modified Ashworth Scale scores of 1–3).</li> <li>Groups: Experimental 13 participants (11 males, 2 females) fitted with a 3D-printed dynamic hand orthosis, and control 12 participants (10 males, 2 females) no splint but followed a home exercise program focused on stretching wrist or finger flexors).</li> <li>Mean age of participants: Experimental group (44), control group (47) years.</li> <li>Tools: Modified Ashworth Scale (MAS), Fugl-Meyer Assessment for Upper Extremity (FMA-UE), Visual Analog Scale (VAS).</li> <li>Measures: Spasticity, motor recovery, and subjective experiences (pain, spasticity, satisfaction, and ease of self-wear).</li> </ul>	<ul style="list-style-type: none"> <li>The experimental group showed significant reductions in spasticity for wrist and finger flexors by 6 weeks.</li> <li>The experimental group reported improvements in motor and sensory functions in the upper extremities.</li> <li>The experimental group also reported longer wearing time, reduced spasticity, higher satisfaction, and ease of use, though pain ratings remained relatively unchanged.</li> </ul>	The 3D-printed dynamic hand orthosis reduces spasticity, improves hand function, and provides high satisfaction for stroke survivors, enhancing home rehabilitation.
Chen et al. [67]	2022	To assess the feasibility of a 3D-printed dynamic hand orthosis for home rehabilitation, focusing on hand strength and functional performance.	<ul style="list-style-type: none"> <li>Participants: 6 male stroke survivors who have a Brunnstrom stage of IV or higher for the proximal upper extremity and stage III or higher for the distal upper extremity.</li> <li>Mean age of participants: 42 years.</li> <li>Tools: Grip gauge, pinch gauge, Action Research Arm Test (ARAT).</li> <li>Measures: Hand strength and function.</li> <li>Methods: Participants underwent a task-oriented training course and were instructed to train at home for 4 weeks, at least 5 days a week, for 40 min per day.</li> </ul>	<ul style="list-style-type: none"> <li>The 4-week home rehabilitation with the 3D-printed dynamic hand orthosis led to significant improvements in grip force, lateral pinch force, and hand function.</li> <li>Grasp and grip scores also improved significantly, while palmar pinch force, pinch scores, and gross movement scores showed trends toward improvement but were not statistically significant.</li> </ul>	The 3D-printed dynamic hand orthosis improved hand strength and function in chronic stroke patients, making it an effective option for home rehabilitation.
Ragni et al. [68]	2023	Design and fabricate a low-cost, functional 3D-printed dynamic upper extremity orthosis (DUEO) and evaluate its impact on upper extremity function in children with unilateral cerebral palsy (CP) at Manual Ability Classification System (MACS) Levels III to V.	<ul style="list-style-type: none"> <li>Participants: 5 children (1 female, 4 males) with cerebral palsy. Their functional level was classified using the Manual Ability Classification System (MACS) as Levels III to V.</li> <li>Mean age of participants: 15 years</li> <li>Tools: Assisting Hand Assessment (AHA), Melbourne Assessment 2 (MA-2), Pediatric Motor Activity Log–Revised (PMAL-R), Pediatric Quality of Life Inventory: CP Module (PedsQL).</li> <li>Measures: Hand function, motor activity, and quality of life.</li> <li>Methods: Assessments were performed pretreatment and immediately post-treatment.</li> </ul>	<ul style="list-style-type: none"> <li>All participants showed higher post-treatment scores on at least one outcome measure.</li> <li>Four participants achieved minimal clinically important differences (MCID).</li> <li>Three participants demonstrated positive changes in upper-limb function, while one experienced a negative change.</li> <li>Four participants showed improvement in both the frequency and quality of use of their affected upper-limb in daily life, with one reaching an MCID score.</li> <li>Three participants reported improvements in their quality of life.</li> </ul>	The 3D-printed DUEO, combined with occupational therapy, improves upper extremity function in children with lower MACS levels, particularly benefiting those with severe hand impairments.

**Table 4** (continued)

Author	Year	Aim	Methods	Results	Conclusion
Madaan et al. [69]	2021	To evaluate the feasibility and use of a 3D-printed Hand-Wrist-Elbow Orthosis (HWEO) for Unilateral Cerebral Palsy (UCP).	<ul style="list-style-type: none"> <li>Participants: 5 (3 males, 2 females) children with unilateral cerebral palsy with a Gross Motor Function Classification System (GMFCS) level of 1 or 2.</li> <li>Mean age of participants: 6 years</li> <li>Tools: Parental reporting, video sharing, and Shriners Hospital Upper Extremity Evaluation (SHUEE) testing.</li> <li>Measures: Goal attainment (using a spoon without spilling) at 3 and 6 months, along with SHUEE testing, which evaluated 16 manual tasks through video analysis to score spontaneous functional analysis (SFA), dynamic positional analysis (DPA), and grasp/release (GRA).</li> </ul>	<ul style="list-style-type: none"> <li>All children used the 3D-printed HWEO for 8–10 h daily, including overnight.</li> <li>While no child achieved the set goals by the final follow-up, all 3 children (with a minimum follow-up of 3 months) showed improvement in upper-limb function without significant safety concerns.</li> <li>There were no new deformities, pressure sores, or injuries related to the 3D-printed HWEO.</li> <li>Two out of five children experienced issues with misfit, and frequent 2 s required repairs.</li> </ul>	The 3D-printed HWEO shows promise in improving upper-limb function in children with unilateral cerebral palsy.
Chhikara et al. [70]	2023	Develop and evaluate a 3D-printed dynamic upper extremity orthosis (DUEO) for spinal cord injury (SCI) patients to assist with activities of daily living (ADLs).	<ul style="list-style-type: none"> <li>Participants: 10 individuals with an incomplete cervical spinal cord injury (SCI) (Genders were not specified).</li> <li>Mean age of participants: 37 years.</li> <li>Tools: QUEST 2.0 Questionnaire and time measurement (verbal feedback).</li> <li>Measures: Time taken to complete ADLs, user satisfaction, and effectiveness of task completion.</li> </ul>	<ul style="list-style-type: none"> <li>The multipurpose 3D-printed DULO achieved high satisfaction scores.</li> <li>Patients independently performed ADLs such as brushing, eating, and writing.</li> <li>Initially, ADL completion times were longer when using the 3D-printed DULO compared to conventional orthoses, but after four weeks of use, efficiency improved.</li> <li>Regular follow-ups confirmed patient comfort and adherence, with task times decreasing over time while using the 3D-printed orthosis.</li> </ul>	The 3D-printed DULO improves efficiency in performing ADLs for individuals with SCI, offering significant benefits
Butnaru-Moldoveanu et al. [71]	2023	To develop and evaluate a 3D-printed dynamic upper extremity orthosis (DUEO) for post-stroke rehabilitation, with a focus on usability and effectiveness.	<ul style="list-style-type: none"> <li>Participants: 5 Healthy participants. (Genders were not specified)</li> <li>Mean age of participants: Not provided</li> <li>Tools: System Usability Scale (SUS).</li> <li>Measures: System Usability Scale (SUS) scores, device performance (mechanical properties and operational efficiency), weight and portability of the orthosis, and qualitative user feedback on comfort and design.</li> </ul>	<ul style="list-style-type: none"> <li>The 3D-printed DUEO indicated overall “good” to “excellent” usability.</li> <li>The 3D-printed DUEO was well-received for its performance, light-weight design, and portability.</li> </ul>	The 3D-printed orthosis is safe, easy to use, and effective for passive elbow and forearm movement, making it ideal for post-stroke at-home rehabilitation.
Toth et al. [72]	2020	Develop a cost-effective, lightweight, and ergonomic 3D-printed dynamic hand orthosis for post-stroke patients to improve upper-limb function through home therapy.	<ul style="list-style-type: none"> <li>Participants: 6 (4 females, 2 males) Chronic post-stroke patients suffering from spastic hand paralysis. Spasticity levels were measured using the Modified Ashworth Scale (MAS), with scores ranging from 2 to 3+.</li> <li>Mean age of participants: 42 years.</li> <li>Tools: Leap Motion Controller (LMC), Manual Function Test (MFT), ADL Test, and Digital Microscope.</li> <li>Measures: Mechanical durability through 300 heating cycles, functional improvements in manual tasks and ADLs, hand movement analysis, and patient satisfaction.</li> </ul>	<ul style="list-style-type: none"> <li>The 3D-printed dynamic hand orthosis demonstrated mechanical durability and significantly improved functional performance in manual tasks and ADLs.</li> <li>The 3D-printed dynamic hand orthosis provided effective assistance in finger extension and reduced movement asymmetry.</li> <li>Patient satisfaction was high.</li> </ul>	The lightweight, 3D-printed dynamic hand orthosis with nitinol smart alloys improves hand function in post-stroke patients, offering durability, cost-effectiveness, and enhanced rehabilitation.

insoles depends on design precision, material selection, and patients’ needs, thus, further research on optimizing the biomechanical and clinical benefits of 3D-printed insoles is needed.

### 3D-printed foot ankle orthosis

Table 2 shows studies on 3D-printed AFOs with two studies classified as “Good” and 1 as “Fair” according to the Modified Downs & Black checklist. These studies have utilized motion capture, force plates, Electromyography (EMG), plantar pressure measurement systems,

**Table 5** 3D-printed helmets

Author	Year	Aim	Methods	Results	conclusion
Kropla et al. [73]	2023	Develop a 3D-printed helmet to improve comfort, weight, fit, and user-friendliness.	<ul style="list-style-type: none"> <li>Participants: 15 infants (4 females, 11 males) with asymmetrical skull shapes.</li> <li>Mean age of participants: 12 months or younger (mean not provided)</li> <li>Tools: 3D scanner, 3D printer, and verbal feedback (scheduled follow-ups)</li> <li>Measures: Geometric measurements of the skull</li> </ul>	<ul style="list-style-type: none"> <li>Positive feedback on the design, ventilation system, and innovation of the interchangeable inner component of the helmet.</li> </ul>	The 3D-printed helmet enhanced comfort, ventilation, and a customizable fit, reducing the need for reprints while supporting ongoing therapy.
Aihara et al. [74]	2024	Investigate factors affecting cranial molding helmet therapy (CMHT) effectiveness, timing, and prognosis for Positional Plagiocephaly and Brachycephaly (PPB) in infants to optimize treatment strategies.	<ul style="list-style-type: none"> <li>Participants: 2,173 infants (704 females, 1469 males) with Positional Plagio and/or Brachycephaly (PPB) of moderate to severe degree.</li> <li>Mean age of participants: 7 months</li> <li>Tools: 3D scanner and 3D printer.</li> <li>Measures: Geometric measurements of the skull.</li> <li>Methods: Assessment before and after fitting a 3D-printed helmet.</li> </ul>	<ul style="list-style-type: none"> <li>Significant improvements, including a more symmetrical skull shape ratio, were observed in cranial deformities after fitting a 3D-printed helmet.</li> <li>Longer therapy duration was correlated with greater symmetry improvements</li> </ul>	While age affects 3D-printed helmet effectiveness, the degree of deformity (DoD) has a greater impact on symmetry improvements. A predictive model with cranial parameters can enable effective treatment of PPB in older infants, highlighting the importance of early DoD detection.

manual measurement tools, and rehabilitation outcome measures. Two studies [52, 53] introduced 3D-printed AFOs with posterior struts to improve gait parameters and balance in patients with drop foot or other lower-limb impairments. However, Harper et al. [53] reported that the stiffness of 3D-printed AFOs does not significantly affect walking performance. Fu et al. [54] designed 3D-printed hinged AFOs for individuals with hemiplegia due to stroke. Their findings suggest that these AFOs can increase medial midfoot pressure, promote a more symmetrical gait, and encourage medial weight-bearing.

Promising advantages can be predicted for the future of 3D-printed AFOs, as the most up to date studies indicate a high potential of improving stability and all in all gait performance for challenged patients. Hinged 3D-printed AFOs can redistribute loading onto plantar pressure points to enhance gait symmetry, specifically for hemiplegic patients. Though various designs and assessment tools were employed throughout the studies which presented valuable results, the need for continuing research still persists to validate findings.

### 3D-printed spinal orthosis

Five studies [14, 55–58] evaluated 3D-printed spinal orthoses for scoliosis. Most of these studies used radiographic systems to measure the Cobb angle and reported various rehabilitation outcomes. All studies found that the 3D-printed spinal orthosis is effective in treating scoliosis, with a reduction in the Cobb angle [14, 55–58]. Additionally, pain relief was reported in one study [55], and improvements in quality of life were observed in others [56, 57]. When comparing 3D-printed orthoses to thermoplastic orthoses, results indicated a reduced need for surgeries [57], and the 3D-printed versions were thinner, lighter, cheaper, and required less manufacturing time [58]. Lastly, Storm et al. [14] concluded

that 3D-printed orthoses could replace thermoplastic versions, offering similar effects on postural stability in patients with Osteogenesis imperfecta and idiopathic scoliosis while increasing production efficiency.

As shown in the studies, 3D-printed spinal orthoses not only proved to be effective in reducing the severity of a scoliotic spine, but also provided pain relief, thus improving overall quality of life. 3D-printed orthoses' manufacturing ease in comparison to conventional thermoplastic orthoses highlighted their efficiency and cost effectiveness. Thus, studies have brought forward a promising future for spinal orthotic management and reducing the efforts of clinical practitioners as well.

### 3D-printed upper-limb orthosis

The studies compared 3D-printed upper-limb orthoses based on different designs [65, 68–72], material [11, 12, 59, 62, 65], types [11, 60, 61, 63], and methods [64]. They utilized radiological systems to assess the effectiveness and improvement [8, 11, 12, 59–64, 66, 70].

Most studies on 3D-printed upper-limb orthoses have focused on wrist splints [8, 11, 12, 59–63]. Graham et al. [11, 59] and Xiao et al. [12] compared the effectiveness and satisfaction of 3D-printed wrist splints versus fiberglass wrist splints. Both 3D-printed and fiberglass wrist splints provide similar immobilization functions for patients with displaced distal radius fractures [11, 59], but satisfaction and comfort were higher for the 3D-printed wrist splints compared to fiberglass ones [11, 59]. 3D-printed and thermoplastic wrist splints are also effective for treating Colles' fractures, but 3D-printed wrist splints offer better clinical performance, imaging outcomes, and patient satisfaction [12]. Skibicki et al. [8] reported that patients with fractures healed in an excellent position while fitted with both 3D-printed and fiberglass splints. However, significant differences were found

in terms of skin irritation, comfort, satisfaction, and cast care, favouring 3D-printed wrist splints over fiberglass wrist splints [8]. Oud et al. [60, 61] and Zheng et al. [62] focused on treating individuals with chronic hand conditions. 3D-printed hand splints match conventional ones in function and quality of life [61], reduce pain, improve hand function, enhance quality of life, and support the use for such cases [60]. Additionally, 3D-printed wrist splints are comfortable and lower costs compared to the conventional wrist splints [61]. Zheng et al. [62] found that 3D-printed hand splints effectively reduce spasticity, and swelling, and improve wrist function, offering better personalization and support as a rehabilitation tool for individuals with hemiparetic due to stroke [62]. Finally, Kim et al. [63] concluded that 3D-printed wrist splints provide similar pain relief and functionality to ready-made ones while offering superior user satisfaction, making them a viable alternative [63].

Portnoy et al. [64] evaluated the effectiveness of the 3D-printed finger splints in treating swan-neck deformity. Occupational therapy students reported that 3D-printed finger splints can simplify clinic workflows by improving customization, efficiency, fit, and aesthetic appearance for different levels of finger deformities [64]. Huber et al. [65], Yang et al. [66], and Chen et al. [67] fitted stroke survivors with 3D-printed dynamic hand orthoses with finger extension assist. They found that this type of 3D-printed orthosis is feasible [65], reduces spasticity [66], improves hand function and strength [33, 66], and can be with different stiffness [65].

Four studies investigated the effects of 3D-printed dynamic upper extremity orthosis (DUEO) [68–71] on patients with cerebral palsy (CP) [68, 69], spinal cord injury (SCI) [70], and stroke [71, 72]. Ragni et al. [68] and Madaan et al. [69] reported that the 3D-printed DUEO, combined with occupational therapy, improves upper extremity function in children with CP, particularly those with severe hand spasticity [68, 69]. Chhikara et al. [70] concluded that 3D-printed DULO is safe, easy to use, and effective for post-stroke survivors due to the passive elbow and forearm movement, hence, it is ideal for at-home rehabilitation [70]. Butnaru-Moldoveanu et al. [71] reported that 3D-printed DULO improves efficiency in performing ADLs for individuals with SCI [71]. Toth et al. [72] introduced a lightweight 3D-printed DUEO with nitinol smart alloys that would improve hand function in post-stroke patients, offering durability, cost-effectiveness, and enhanced rehabilitation [72].

According to the studies, the provided immobilization by both 3D-printed and traditional orthoses was similar, the significance mainly was in the improved satisfaction and comfort experienced by patients who were fitted with 3D-printed upper-limb orthoses. Considering the patient's positive feedback alongside radiological

assessments, 3D-printed upper-limb orthoses appear to be quite promising and may become a valuable alternative.

### 3D-printed helmets

The tools used across the studies including a 3D scanner, a 3D printer, and rehabilitation outcome measures. Two studies used 3D scanning to treat cranial deformities, including positional plagiocephaly and brachycephalic [73, 74]. These studies found that 3D-printed helmets enhanced comfort and fit, reduced treatment duration, and improved skull symmetry, particularly in cases with a higher degree of deformity. However, longer therapy and greater deformity severity had the most significant impact on the effectiveness of the helmets.

3D-printed helmets proved to be effective when used to treat cranial deformities such as plagiocephaly. The studies highlighted the comfort and fit achieved by 3D-printed helmets, as well as reducing treatment duration and reaching more improved skull symmetry. Thus, it has been made evident by the studies that 3D-printed helmets can be successfully employed to effectively treat cranial deformities in infants, allowing a proper custom fit which leads to efficient results.

While the clinical benefits observed in this review, such as improved gait parameters, reduced plantar pressures, enhanced comfort, and increased patient satisfaction, are promising, it is crucial to differentiate between outcomes due to the orthotic intervention itself and those attributable to the manufacturing method (3D-printing vs. traditional). In several included studies, both traditionally made and 3D-printed orthoses showed comparable effects in terms of biomechanical support and pain relief, suggesting that the orthotic design may play a more central role than the production method alone. However, advantages unique to additive manufacturing, such as improved personalization, reduced weight, faster turnaround, and patient-reported satisfaction, support its clinical relevance. Thus, while clinical outcomes may not always be significantly superior, 3D-printing offers practical, logistical, and customization advantages that could influence patient adherence and long-term outcomes. Future comparative trials are warranted to isolate the effects of design vs. fabrication method more precisely.

Additionally, device-specific features such as modelling approach, infill design, and material stiffness influenced biomechanical outcomes. Toth et al. [72] and Huber et al. [65] demonstrated that material stiffness in upper-limb orthoses impacted hand performance, with higher stiffness reducing pincer force and fine dexterity. Similarly, Fu et al. [54] and Harper et al. [53] showed that stiffer AFOs affect medial ground reaction forces and gait symmetry.

In general, 3D-printed insoles, AFOs, spinal orthoses, upper limb orthoses, and helmets demonstrated

good durability across multiple studies. Shaikh et al. [45] reported over 16 months of use for insoles, and short-term studies noted no significant damage [32, 50]. As for 3D-printed AFOs, studies reported that they are more durable than traditional ones. Harper et al. [53] demonstrated that 3D-printed AFOs were able to withstand high forces without breaking. While other studies confirmed improved long term performance [52], and patients reporting better durability [54]. Studies on 3D-printed spinal orthoses showed that the durability is more dependent on the design quality. Storm et al. [14] reported cracking within two weeks in certain cases, while Lou et al. [58] reported no damage after two years of use. Studies on 3D-printed upper limb orthoses demonstrated good durability, with no significant breaks reported. Only splint breakage in delicate or hinged designs was reported [69]. Finally, 3D-printed helmets were found to be structurally stable with reinforced and modular designs that support long term use [73, 74].

Although most orthoses demonstrated acceptable performance, mechanical durability testing such as heating cycles or user-reported failures remain inconsistently addressed. Future research should incorporate standardized real-world testing and focus on material resilience and fatigue life to ensure long-term success.

#### Study limitation and future recommendation

This review has several strengths, including a comprehensive multi-database search, adherence to PRISMA guidelines, and inclusion of a wide range of orthotic types and clinical outcomes. However, certain limitations must be acknowledged. To ensure broad coverage of available literature, we included various study designs, including case series. While this enhances inclusivity, it may reduce the overall level of evidence. Many included studies featured small sample sizes or short follow-up durations, limiting the ability to generalize findings. Additionally, the heterogeneity in study designs, outcome measures, and participant characteristics precluded direct comparisons and meta-analysis. A notable methodological issue was the lack of standardized evaluation tools. Different questionnaires were often used to assess the same outcomes such as patient satisfaction making cross-study comparisons difficult. Furthermore, no eligible studies were found on some common orthotic types such as knee–ankle–foot orthoses (KAFOs), highlighting a gap in the literature. Finally, while approximately half of the included studies were rated as good quality, others presented risks of bias due to unclear blinding procedures or limited statistical power. Future research should focus on large-scale, high-quality trials employing standardized outcome measures, and explore long-term durability, patient adherence, and cost-effectiveness of 3D-printed orthoses.

#### Conclusion

The reviewed studies demonstrate the advancement of 3D-printing in the manufacturing of orthoses including insoles, AFOs, spinal orthoses, upper-limb orthoses, and helmets. The results show that 3D-printed orthoses lead to improvements in gait parameters, functional performance, radiographic measurements, comfort, fit, and overall effectiveness. The methodological quality of the included evidence was mostly rated as “Good” or “Fair”, which supports these findings, despite one study being rated ‘Poor’. While some limitations were reported in the reviewed studies, further research could address these limitations and provide solutions that can further advance the use of this technology.

#### Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12891-025-09070-4>.

Supplementary Material 1.  
Supplementary Material 2.  
Supplementary Material 3.  
Supplementary Material 4.

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#### Authors' contributions

Conceptualisation, H.A.; methodology H.R.B and T.Q.; formal analysis T.Q.; investigation H.A.; data curation T.Q.; writing—original draft preparation H.A, T.Q.; writing—review and editing, H.R.B. and G.F; supervision, H.A. All the authors have read and agreed to the published version of the manuscript.

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#### Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

#### Declarations

##### Ethics approval and consent to participate

Not applicable.

##### Consent for publication

Not applicable.

##### Competing interests

The authors declare no competing interests.

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