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Biomechanical and Perceived Comfort Analysis of FDM 3D-Printed Insoles for Flatfoot Treatment: A Systematic Literature Review

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ABSTRACT

Flatfoot (pes planus), characterized by a reduced or absent medial arch, cause biomechanical disorders, pain and a risk of injury. Customized insoles are a key intervention, with the emergence of 3D printing fused deposition modelling (FDM) based on flexible materials such as thermoplastic polyurethane (TPU) and thermoplastic elastomer (THE). This systematic literature review, based on PRISMA guidelines and analysis of six Scopus studies, assesses the biomechanical and ergonomic properties of these insoles. The results show that flexible 3D printed inserts significantly improve biomechanics by increasing the height of the navicular arch, reducing excessive ankle joint eversion, increasing dorsiflexion and improving the distribution of plantar plate pressure. Regarding perceived comfort, evaluations using the Visual Analog Scale (VAS), the Likert scale and the American Orthopaedic Foot and Ankle Society (AOFAS) questionnaire consistently indicate improved user comfort over no insole or conventional option. Despite these advantages, challenges include limited material options, inconsistent print quality and technical fabrication problems. Further research is needed, especially large-scale studies, to resolve these problems and to improve the clinical use of the product. In conclusion, flexible inserts printed with FDM have the potential to improve both the biomechanical function and the perceived comfort of the footwear use.

Keywords: flatfoot; 3D printing; FDM; flexible material; biomechanics; perceived comfort; systematic literature review

INTRODUCTION

Flatfoot or pes planus is a condition in which the medial arch of the foot decreases or disappears, causing the sole of the foot to almost completely touch the ground when standing [1], [2], [3]. The normal arch structure of the foot plays a role in distributing pressure and supporting body weight during daily activities. In individuals with flatfoot, ligament and tendon weakness results in biomechanical disturbances that can cause pain and increase the risk of injury [4]. One of the main solutions to reduce discomfort due to this condition is the use of foot orthotics or insoles, which serve to support the arch of the foot and improve load distribution to increase stability and comfort while walking [5]. However, traditional orthoses manufacturing methods face limitations in terms of material-wasting, time-consuming, and labor-intensive process. 3D Printing technology has advantages that can solve these problems [6].

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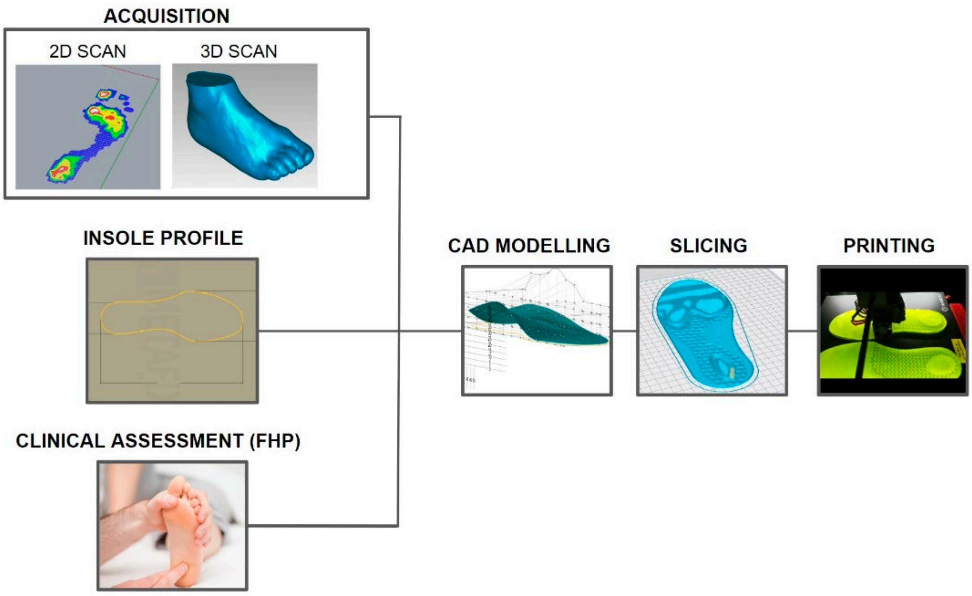

Figure 1. Manufacturing workflow for designing customized 3D-printed insoles [12]

In foot orthotic development, 3D printing technology has become an innovative production method that offers various advantages over conventional techniques. This technology allows for more precise insole manufacturing, high personalization, and is time and cost-efficient [7], [8]. One of the most commonly used 3D printing methods is Fused Deposition Modeling (FDM), which is popular due to its simplicity, lower equipment costs, and compatibility with various types of polymeric materials [9]. With FDM technology, insole manufacturing can be individually customized based on a 3D scan of the patient's foot, providing a better fit than off-the-shelf orthotic products [10], [11]. The overall workflow for designing and producing customized 3D-printed insoles—from foot scanning, digital modeling, and slicing to final fabrication—is illustrated in Figure 1.

The selection of flexible materials in insole fabrication is crucial to achieve the right balance between comfort and biomechanical support. For orthotic insoles, the material must provide sufficient rigidity to support the foot structure while also offering the necessary elasticity and durability to ensure comfort and biomechanical efficacy during gait [13], [14], [15]. One frequently used material is Thermoplastic Polyurethane (TPU), which has high flexibility, good mechanical and chemical resistance, and biocompatibility that makes it suitable for medical devices, wearable electronics, and automotive components [16]. In the context of flatfoot insoles, TPU is known for its excellent flexibility and elasticity, which are crucial for providing comfort in insoles [17], [18] . TPU also offers excellent resistance to abrasion and impact, making it durable enough to withstand the repetitive stress of daily walking [17], [18]. Additionally, its biocompatibility ensures that the insole is safe for prolonged contact with the skin [19], which is critical for patient comfort and safety.

In addition, Thermoplastic Elastomers (TPE) have many physical properties similar to rubber, such as softness, flexibility, and resistance to deformation [20]. These characteristics make TPE ideal for providing cushioning and comfort in insoles [21], [22], [23]. The superior mechanical properties of TPE, including high tensile strength and resistance to stretching, which is essential for insoles that need to support the foot over extended periods [24], [25] and ensures the insoles can withstand the stresses of daily use without tearing or losing their supportive function [25], [26]. With the development of these flexible materials, FDM-printed orthotics can have the ideal combination of durability, flexibility, and user comfort, all of which are crucial for improving foot biomechanics in flatfoot patients. An example of the personalized insole fabrication process using flexible materials is illustrated in Figure 2.

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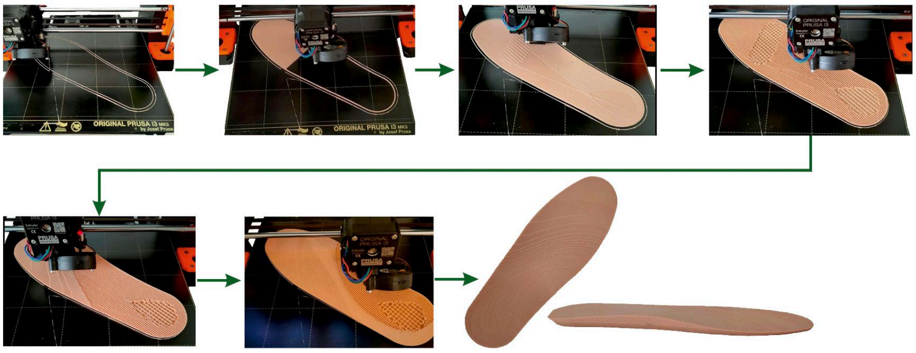

Figure 2. Example of the 3D printing process for an insole made from flexible material [28]

Despite the growing use of FDM in orthotic insole development, no prior systematic review has comprehensively assessed the biomechanical and comfort-related outcomes of flexible materials specifically for flatfoot treatment. Previous research has not addressed flexible materials for insoles, even though these materials are continuously evolving and are frequently used in 3D printing due to their various positive properties, making them an ideal choice for insole manufacturing. This lack of consolidated, evidence-based guidelines poses a significant barrier to clinical adoption, as practitioners are faced with a fragmented body of literature that often yields inconsistent efficacy findings. The gap arises from insufficient integration of studies that address the complex interplay between material properties and biomechanical outcomes. To overcome these limitations, this review aims to provide a comprehensive synthesis that reconciles existing discrepancies, evaluates the methodological quality of current research, and clarifies how different flexible materials affect the biomechanical performance and comfort of 3D-printed insoles for flatfoot treatment. By conducting a Systematic Literature Review, this research aims to identify the advantages and challenges in the use of flexible materials for 3D-printed insoles, thereby providing a foundation for the development of more ergonomic and functional orthotic designs. In this review, biomechanical impact is evaluated through outcomes such as kinetics and kinematics aspects, while perceived comfort encompasses patient-reported outcomes. The findings of this study are expected to provide new insights into formulating clinical recommendations and encourage further innovation in the field of additive manufacturing for foot orthotics to improve the quality of life for individuals with flatfoot. This systematic review will be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure a comprehensive and reproducible search, selection, and synthesis process.

METHODS

A This section defines the materials and methods used in this systematic review. The selection of a robust methodological framework has been made to ensure the validity and reliability of the results and to ensure transparent reporting, which will facilitate replication in future research. The investigation was focused on two main research issues:

RQ1. What are the biomechanical impacts of the use of 3D printed insoles using FDM and flexible materials?
RQ2. How comfortable are the insoles made using 3D printing technology with FDM and flexible materials?

A structured data search strategy has been put in place to address these questions. The search process is used to obtain relevant sources to answer the Research Question (RQ) and other related references. The search process is conducted using a search string (TITLE-ABS-KEY ("flatfoot" OR "flatfeet" OR "pes planus" OR "low arch") AND TITLE-ABS-KEY ("insole" OR "orthos*" OR orthotic* OR "arch support")). This search string was initially used to filter studies related to foot orthotics for individuals with flatfoot in the Scopus database, providing a total count of publications discussing foot orthotics for flatfoot sufferers. After obtaining these studies, a manual filtration process was performed to exclude papers that did not specifically discuss 3D-printed insoles. This allowed us to identify studies focused on 3D-printed insoles for flatfoot. Next, the filtered studies were further examined based on their full content to identify those that discussed the use of flexible materials and their impact on biomechanics and user comfort. This two-step filtering process ensured that only the most relevant studies were included in the review.

The database source used for literature searches in this study is Scopus until 31 January 2025. The study exclusively relied on the Scopus database for literature searches to minimize potential discrepancies in data and field tags that could result from using multiple databases. Moreover, the Scopus database offers a higher volume of citations and articles [28]. It includes over 14,000 scientific journals and various sources with daily updates [29].

Clear eligibility criteria have been established to determine the suitability of a study. The inclusion criteria for this study are as follows: (1) the articles must be scientific journals and/or proceedings, (2) written in English, (3) focus on participants who are individuals diagnosed with flatfoot, confirmed either clinically or radiographically, (4) the study must discuss the biomechanical effects or comfort aspects of 3D-printed insoles, and (5) the material used to print the 3D insole must be flexible. The exclusion criteria are as follows: (1) studies focusing on other foot pathologies (e.g., bunions, heel spurs), (2) review articles, editorial letters, and studies not involving original research, (3) studies not written in English, (4) using non-flexible materials or non-FDM 3D-printed insoles, and (5) studies that do not focus specifically on insoles designed for flatfoot treatment. It should be noted that the language restriction to English-language studies may introduce a potential source of bias, as studies published in other languages are excluded.

The quality of the articles in this study was independently evaluated by two reviewers (TAP and AN) using the Combie criteria, which includes seven evaluation aspects for cross-sectional studies [1]: (C1) The study's design is scientific; (C2) the data collection strategy is reasonable; (C3) the research reports sample response rates; (C4) the population's representation of samples is very good; (C5) the research purpose and method are reasonable; (C6) The study reports the statistical power of the data; and (C7) The correctness of statistical method used. Each evaluator assigns a “yes”, “no”, or “unclear” value for each assessment aspect. Based on the Combie evaluation instrument, a "yes" will be worth 1.0; a "no" will be worth 0.0; and an "unclear" will be worth 0.5. Each article can achieve a maximum score of 7.0 points, with quality categories A, B, and C covering scores of 6.0–7.0 points, 4.0–5.5 points, and 0–4.0 points, respectively. If there is a difference of opinion in the assessment, an independent mediator will be involved to reach an agreement (KAN).

For the data synthesis, the study selection process followed the PRISMA (Priority Reporting Items for Systemic Reviews and Meta-analyses) guidelines closely as illustrated Figure 3. Finally, data extraction was carried out and the results were summarised in tables. One table captured the main study characteristics (researchers, year of publication, biomechanical focus, method of comfort measurement, duration of intervention, subjects), while a separate table provided detailed information on the flexible materials, printing types, key biomechanical findings and study conclusions. This improves structure and readability of data.

RESULTS AND DISCUSSION

Literature selection

The selection process for this study was carried out systematically using the PRISMA methodology, which outlines four key phases: identification, screening, assessment of eligibility and inclusion in the study. In the identification phase, 765 records from Scopus were obtained. 297 records were excluded before being screened for a number of

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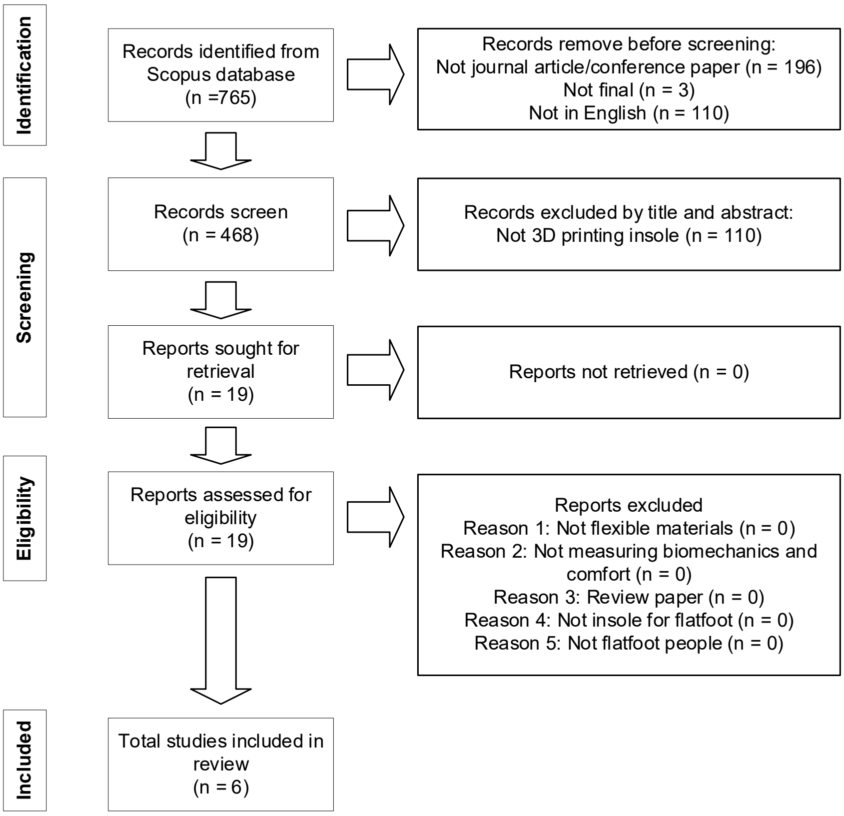

Figure 3. Data synthesis using PRISMA

reasons: 196 were not journal articles or conference papers, 3 were incomplete or not final documents and 110 were not in English. That left a total of 468 records to be reviewed. The screening phase included the examination of the titles and abstracts of these 468 records. During this procedure, 449 records were excluded from the review as they were not relevant. The remaining 19 records were considered potentially relevant and were downloaded in their entirety for a more detailed assessment. All 19 articles were accessible and therefore none of them was excluded because of access problems. In the next stage of the eligibility assessment, 19 full text articles were assessed on the basis of pre-defined criteria. Several studies have been excluded at this stage: 13 studies did not use flexible materials, 2 did not measure biomechanical or comfort aspects, 1 was a review study, 2 did not address flat-sole insoles and 1 did not include patients with flat feet. The inclusion phase finally resulted in six studies meeting all criteria. These studies were included in the final review because they specifically examined 3D printed flexible-material insoles for flat-footed patients, with a focus on comfort and biomechanical effects.

The displayed PRISMA diagram provides transparency in the literature selection process, ensuring that only articles meeting high-quality standards and research relevance are used in the analysis.

Original characteristics

A review of studies on biomechanics and comfort reveals a focus on several key parameters: kinematics (3 studies), kinetics (2 studies), comfort (5 studies). As many as 5 studies combine biomechanical evaluation with comfort, while the rest only measure comfort. Geographically, the distribution of the studies was conducted by researchers from Japan, Thailand, the Slovak Republic, India, Taiwan, and China. The sample sizes vary with 1 study involving only 1 sample, 2 studies involving 10 to 20 people, 1 study involving 50 people, and 1 study involving more than 150 samples. In this literature review, studies focused solely on measuring comfort typically involve larger sample sizes, with 3 studies using questionnaires and involving more than 50 participants. In contrast, studies evaluating biomechanical parameters generally involve fewer participants, typically fewer than 20 individuals. This disparity in sample size can be attributed to the complexity and resource intensity of biomechanical or laboratory-based evaluations compared to questionnaire-based studies, which are less resource-demanding and easier to recruit participants for. Factors such as ethical considerations, data quality requirements, and technological constraints inherent in biomechanical research also contribute to the smaller sample sizes in these studies [30], [31], [32], [33], [34], [35]. In terms of the participants' gender, 1 study involved male participants, 1 study involved female participants, 3 studies involved mixed gender participants, and 1 study did not specify. As many as 3 studies focused solely on walking activities, 1 study focused only on running activities, and the rest were a combination of several activities such as standing, walking, and running.

Risk of Bias

The risk of bias in all selected studies has been evaluated, and the results are detailed in Table 1. From the evaluation conducted, 50% of the studies have quality A (high), while 50% of the studies are classified as quality B (moderate). No studies fell into the quality category C (low) with a score below 4.0 points. Therefore, the literature selected in this study is assessed to have high to moderate quality, making it reliable for further analysis. However, it is important to note that 5 out of 6 studies did not report the power of the test. The absence of power calculations in scientific studies is a significant concern because it frequently results in underpowered research. Underpowered studies diminish research validity and efficiency, contributing to issues such as a higher risk of Type II errors, inflated effect sizes, poor reproducibility, and ethical concerns due to insufficient probability of generating valuable information [36]. Additionally, only half of the studies clearly reported sample response rates, which could affect the interpretation of their findings. Papers that omit sample response rates are weak because they prevent assessment of nonresponse bias, undermining the generalizability and credibility of findings, and complicating replication [37].

Flexible Insoles for Flatfoot Treatment Made using FDM 3D Printing Technology

3D printing technology, particularly through the Fused Deposition Modeling (FDM) method, makes a significant contribution to the production of flexible insoles for the treatment of flatfoot. Advancements in 3D printing and scanning technology enable the digitalization and personalization of foot orthoses with greater accuracy. The foot scanning procedure, which serves as the initial stage for generating accurate digital foot models prior to insole design and printing, is illustrated in Figure 4.

This technology allows for the creation of orthoses that closely match the contours of each individual's foot, offering more optimal support for the foot arch. The uniqueness of each flat foot can be addressed more efficiently with this

Table 1. Study Risk of Bias Assessment

Studies	Evaluation Aspects							Grade	Quality
	C1	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**		
[11]	Yes	Yes	Yes	Yes	Yes	No	Yes	6	A
[38]	Yes	Yes	Yes	Yes	Yes	No	Yes	6	A
[39]	Yes	Yes	Unclear	Yes	Yes	No	Yes	5.5	B
[12]	Yes	Yes	Unclear	Yes	Yes	No	Yes	5.5	B
[27]	Yes	Yes	No	Yes	Yes	No	Yes	5	B
[40]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	A

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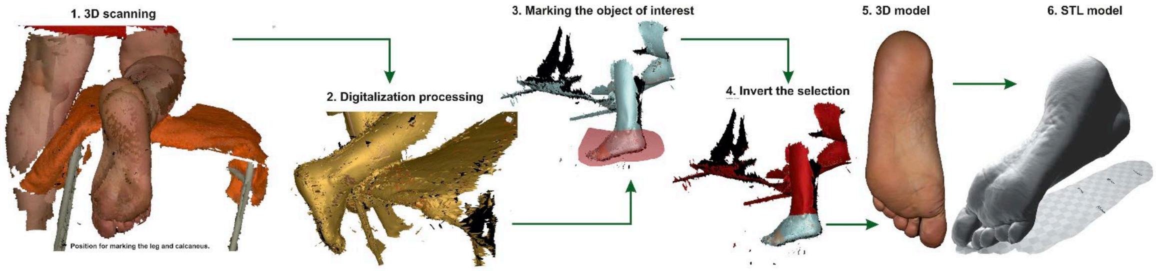

Figure 4. Foot scanning procedure [27]

technology. Additionally, 3D printing accelerates the manufacturing process and facilitates the use of various types of materials, enhancing the comfort and function of the orthosis. In general, 3D printing technology offers more personalized and innovative solutions to address flatfoot issues [38], [41]. The reviewed studies consistently leveraged the personalization capability of Fused Deposition Modeling (FDM), with all six articles basing their insole designs on 3D foot scans. This personalized approach was identified as a key factor for improving biomechanical effects and comfort scores, as demonstrated by [11], [12], [27], [38], [39], [40].

Thus, the application of FDM technology in the production of flexible insoles not only allows for higher personalization but also opens up various new possibilities in the design and function of orthoses. One of the main advantages of FDM is the relatively low equipment cost, making it an ideal choice for small industries such as footwear manufacturing. This 3D printing system can use various polymer materials in its production. The application of FDM technology in the production of insoles opens up new possibilities in manufacturing that cannot be achieved with conventional methods, as it allows for the addition of new features to the insoles. This process, known as functionalization, allows for the integration of additional components that can enhance the characteristics of the insole, including structural modifications such as the creation of cavities that affect impact absorption and flexibility [42]. Table 2 summarizes various studies on the application of FDM in the production of foot orthotics for flatfoot using flexible materials.

Tabel 2. Summary of various studies on the application of FDM additive manufacturing in foot orthotic products for flatfoot using flexible materials

Studies	Year	Printer	Material	Printing Parameters
[11]	2021	IFOOT-DK3, Shenzhen, Guangdong, China	polyurethane elastic	Not mentioned
[38]	2021	iSun3D Flx2, eSUN Industrial Co. Ltd., Shenzhen, China	eTPU-95A (Shenzhen Esun Industrial Co. Ltd., Shenzhen, China)	Printer nozzle: 0.8 mm Nozzle: temperature: 235 ◦C. Layer Thickness: 0.4 mm Infill Pattern: triangle
[39]	2022	Joy Sunrise Research Inc., Taipei, Taiwan	TPU	Nozzle temperature: 250 °C. Printing velocity: 30 mm/s Layer Thickness: 0.2 mm
[12]	2023	JGMaker, Ultimaker, dan Raise3D printers	TPU 90A and 95A	Not mentioned
[27]	2023	Prusa i3 MK3S, Czech Republic	TPU, Filaflex 82A	Not mentioned
[40]	2024	Not mentioned	Thermoplastic elastomer	Not mentioned

In addition, the material used in the production of insoles also plays an important role in ensuring the comfort and effectiveness of orthosis use. One of the polymer materials often used to produce foot orthoses with FDM technology is TPU (Thermoplastic Polyurethane). TPU material is widely used as a foot orthotic material that employs 3D printing technology due to its various advantages. TPU, when compared to other commonly used raw materials for 3D printing, such as polyethylene terephthalate (PETG), acrylonitrile butadiene styrene (ABS), and polylactic acid (PLA), stands out in terms of properties relevant for insole applications. One of its advantages is its softness, which makes it a material that is not too hard, flexible, with good elasticity, and resistant to moisture [43]. In addition, TPU material is flexible, has hydrolysis resistance, high resistance to bacteria, is non-toxic, can come into contact with skin, and can be used immediately without post-processing [27]. The use of TPU material is very effective, inexpensive, and highly resistant to mechanical stress [12]. Neither PLA nor ABS meet the mechanical properties required for insoles that are fully loaded for daily use [27]. In addition to TPU, elastic polyurethane and thermoplastic elastomer materials are also used in the production of foot orthoses with FDM technology [11], [40].

Biomechanical and Comfort Evaluation

Several studies have evaluated the biomechanical effects and comfort of using flexible foot orthoses printed with 3D Printing, particularly in individuals with flatfoot. Table 3 presents a summary of the biomechanical and comfort evaluation of the use of flexible foot orthotics based on 3D Printing (3DP) technology for individuals with flatfoot.

Table 3. Summary of the biomechanical evaluation and comfort of 3D-printed foot orthotics for flatfoot with flexible materials

Studies	Biomechanical Evaluation	Comfort Evaluation	Usage period	Number of respondents
[11]	N/A	AOFAS Questionnaire	1 years; min 4h per day during their regular daily activities	50 patients (19 males and 31 females) with flatfoot, aged 26.3 ± 19.9
[38]	Kinematics: – Rearfoot angle – Ankle joint angle – Internal rotation – Forefoot angle Kinetics: – GRF – Plantar pressure	N/A	Immediately	10 participants (4 males and 6 females) with flatfoot, aged 20.4 ± 0.9
[39]	Kinematics: – Navicular height – Ankle joint angle Kinetics: – Ankle joint moment – Knee joint moment	Likert Scale 0 – 10	Immediately	10 participants (5 males and 5 females) with flatfoot, aged ≥20
[12]	N/A	AOFAS Questionnaire	Min. 6 months; more than 5 h during their regular daily activities	166 participants with flatfoot, aged 12 years to 77 years.
[27]	N/A	VAS Five-point comfort scale (−4 very uncomfortable, −2 uncomfortable, 0 neutral, +2 comfortable, +4 very comfortable)	3 months; running one km thrice a week	1 woman with bilateral flatfeet, aged 22 years old

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Table 3. Summary of the biomechanical evaluation … (cont.)

Studies	Biomechanical Evaluation	Comfort Evaluation	Usage period	Number of respondents
[40]	Kinematics: • Dynamic navicular drops (mm) • Dynamic navicular drift (mm) • Range of rearfoot angle during stance (°) • Maximum rearfoot eversion during stance (°) • Mean of rearfoot angle during stance (°) • Rearfoot angle at initial contact (°)	VAS	1 month; during their regular daily activities	12 men with flexible flatfoot, aged 18-30

Table 4. Biomechanical Effects of 3D Printed Insoles Made of Flexible Material

Studies	Biomechanical Evaluation	Variable	Effect of Insole 3D Printing
[39]	Navicular height		Increased significantly in all 3D printing insole conditions, especially with the wedge insole.
	Ankle joint angle	Eversion angle peak value	Slightly decreased in scan and total conditions, but increased in wedge condition.
		Dorsiflexion angle peak value	Increased significantly in scan and wedge conditions compared to without insoles.
	Ankle joint moment	Eversion moment	Tends to be lower in the scan and total conditions compared to without insoles, but slightly higher in the wedge condition.
	Knee joint moment	Adduction moment	Slightly increased in total and wedge conditions compared to without insoles, but not significant.
[27]	Plantar force	Toes	The distribution of plantar forces is not very significant in this area; it is more focused on the stability of the metatarsal and midfoot areas.
		Metatarsal	Reducing pressure in the metatarsal area, thereby providing better support when walking and running.
		Midfoot	Improving plantar force distribution in the midfoot area, supporting the foot arch to reduce load in the metatarsal area.
		Rearfoot	The distribution of forces on the rearfoot shows increased stability during high physical activity, such as running.
[38]	Plantar pressure	Medial forefoot	Slight decrease in plantar pressure.
		Lateral forefoot	Plantar pressure is higher in the R+U+ condition compared to without insoles.
		Medial midfoot	Pressure increases significantly under the insole condition with additional arch support.
		Lateral midfoot	Plantar pressure slightly increased under the R+U+ condition.
		Medial hindfoot	Reduction of plantar pressure compared to without insoles.
		Lateral hindfoot	Pressure decreases on the insole condition with additional support. Pressure decreases on the insole condition with additional support.
	vGRF		There is no significant change between the insole conditions in the vertical ground reaction force.
	Rearfoot angle	Hindfoot eversion	Hindfoot eversion tends to decrease in the insole condition, although not significantly.
	Ankle joint angle	Dorsiflexion angle peak value	Significant improvement in dorsiflexion with additional support insoles.
	Internal rotation	Hindfoot internal rotation	There are no significant changes.
		Tibial internal rotation	Tends to decrease under insole conditions.
	Forefoot angle	Forefoot abduction	Tends to decrease under insole conditions, but not significantly.

Table 4. Biomechanical Effects of 3D Printed Insoles … (cont.)

Studies	Biomechanical Evaluation Variable	Effect of Insole 3D Printing
[40]	Dynamic navicular drops (mm)	A significant decrease in the navicular drop value indicates better arch support.
	Dynamic navicular drift (mm)	No significant changes, indicating maintained lateral stability.
	Range of rearfoot angle during stance (°)	There is no significant change in the rearfoot angle range during stance.
	Maximum rearfoot eversion during stance (°)	A significant decrease in the maximum eversion angle helps reduce excessive pronation.
	Mean of rearfoot angle during stance (°)	A significant decrease in the average rearfoot angle during stance improves foot stability.
	Rearfoot angle at initial contact (°)	A significant decrease in the rearfoot angle at initial contact indicates improved foot posture control.

This evaluation includes various aspects, including biomechanical analysis covering kinematic and kinetic aspects, as well as measuring user comfort levels.

Biomechanical Effects of 3D Printed Flexible Insoles for Flatfoot Treatment

Table 4 present more detailed information regarding the biomechanical effects produced by the use of flexible 3D-printed insoles, which include various biomechanical variables that have been evaluated in several related studies.

Kinematics Evaluation

In general, the use of flexible insoles printed using FDM 3D printing technology shows significant improvements in the kinematic parameters of flatfoot patients. The key parameters that have been extensively studied are ankle dorsiflexion angle [38], navicular height [39], [40] and rearfoot eversion angle [38], [39].

The use of a 3D insole with reinforcement and elevation support at the arch of the foot consistently improves dorsiflexion ability at the ankle, which contributes to more flexible and stable foot movement when walking or standing. The use of a 3D insole with foot arch reinforcement and elevation (R+U+ and R-U+) significantly improved ankle dorsiflexion compared to the control condition [38]. This suggests that a flexible 3D insole can help improve ankle range of motion, which is especially important for those with limited motion in the ankle, such as individuals with flexible flat feet. Furthermore, hindfoot eversion and forefoot abduction were two parameters that were also evaluated in the study regarding the use of a flexible 3D printed insole. Although there was a decrease in both aspects, these changes did not reach the level of statistical significance [38].

Other aspects that were the focus of evaluation were navicular height and arch compression. The use of a flexible 3D printed insole can significantly increase the navicular height of the foot compared to the no insole condition [39]. This indicates that the use of a 3D insole contributes to an increase in foot arch height, which occurs due to higher compression when the foot is loaded. This finding is consistent with the findings of Cheng et al. [38], who also showed improved arch stability with the use of a flexible 3D printed insole. The use of an insole with foot arch reinforcement and elevation effectively reduces the pressure acting on the foot arch, allows for more even load distribution, and reduces foot fatigue and discomfort.

On the other hand, the eversion angle at the ankle joint also showed interesting results. The maximum eversion angle at the ankle joint was smaller than that without the use of a flexible 3D printed insole [39]. This is relevant in the

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context of injury prevention, as excessive eversion can cause long-term problems in the foot and knee joints. This is also in line with the results of a previous study by Cheng et al. [38], who found a significant reduction in rearfoot eversion with the use of a 3D insole with flexible materials [38].

In a comparison between a conventional insole, the evaluation results showed that the flexible 3D printed insole provided better results in several kinematic aspects, especially in terms of reduction of navicular dynamic drop and reduction of rearfoot eversion. The use of Cinsole (conventional insole) and 3Dinsole (3D insole) can significantly reduce dynamic navicular drop, as well as reduce the maximum rearfoot eversion angle compared to the condition without insole [40]. This is also in line with research conducted by Cheng et al. (2021) and Hsu et al. (2022) that the 3D printed insole, with a more detailed design tailored to the individual foot shape, is shown to provide more benefits in improving foot stability and reducing stresses acting on the arch of the foot [38], [39].

The use of flexible material 3D printed insoles has proven effective in reducing the maximum eversion angle at the ankle joint [38], [39] and increasing the height of the navicular bone [39], [40] compared to conditions without insoles. The reduction in the eversive angle is influenced by various biomechanical factors that play a role in enhancing foot stability and optimizing individual movement patterns. Flexible material insole is designed with medial arch support that helps maintain the natural structure of the foot. With this support, the load distribution on the foot becomes more even and creates a more stable footing, thereby suppressing uncontrolled eversion movements [38], [39], [44]. In addition, this insole plays a role in shaping a more controlled walking pattern, reducing the peak eversion angle and the evertor moment at the ankle joint [44]. Furthermore, 3D-printed insoles have a design that can be customized to the anatomical shape of an individual's foot, thereby improving control over movement, including eversion. Additive manufacturing technology allows for the adjustment of stiffness levels and arch height, which contributes to the reduction of the eversion angle by ensuring the foot remains aligned and well-supported while walking [38], [39], [45]. These flexible insoles also play a role in limiting the range of eversion motion by reducing ankle joint mobility in the frontal plane. Studies show that insoles with additional features such as medial wedges or increased arch stiffness can reduce the maximum eversion angle, which implies improved ankle stability and reduced risk of imbalance during walking [46], [47], [48]. Additionally, the use of flexible 3D-printed insoles helps improve the biomechanical alignment of the lower extremities, meaning the ankle joint position is more neutral, reducing the tendency for excessive eversion, and enhancing biomechanical efficiency during walking activities [39], [49]. With this combination of factors, flexible material 3D printed insoles effectively reduce the maximum eversion angle compared to walking without insoles.

Thus, in addition to contributing to the reduction of the maximum eversion angle and improving ankle stability, flexible 3D-printed insoles also play a role in maintaining the structure of the foot arch. The increase in navicular height when using flexible material 3D printed insoles compared to without insoles can be explained through several biomechanical and structural factors, where one of the main structural factors is arch support and customization that allows the 3D printed insoles to be adjusted to the height and stiffness of the foot arch to optimally support the medial arch, thereby helping to maintain the anatomical position of the navicular bone and significantly increase its height [38], [39], [50]. Additionally, better redistribution of plantar pressure contributes to the elevation of the navicular by increasing the contact area in the midfoot and reducing pressure on the forefoot and rearfoot, thereby helping to maintain the arch of the foot from collapsing or dropping [41], [51]. From a material perspective, the use of thermoplastic polyurethanes (TPU) in the production of insoles allows for a balance between support and comfort, where this material can be configured to provide the right level of stiffness and flexibility to maintain the arch of the foot without causing discomfort [52], [53].

In addition to structural factors, the biomechanical effects produced by 3D-printed insoles also contribute to the increase in navicular height, where several studies have shown that the use of these insoles can enhance navicular height and the angle of ankle dorsiflexion, which helps maintain the foot arch during activities with body load [38], [39]. The comfort factor also plays an important role, as the design of 3D printed insoles ensures proper support in the areas that need it, enhancing user comfort and encouraging longer wear, which ultimately contributes to maintaining optimal navicular height [2], [54].

Kinetics Evaluation

The use of flexible insoles printed using FDM 3D printing technology shows significant improvements in the kinetics parameters of flatfoot patients, particularly in the distribution of plantar pressure and mechanical forces received by the lower limbs [38]. Findings from Cheng et al. [38] demonstrated that the flexible 3D-printed insoles reduced peak pressure in the rearfoot region and promoted a more even load distribution across the midfoot, supporting the medial arch more effectively. The condition without using an insole generally results in pressure accumulation in the heel area due to the lack of support at the medial arch. In contrast, an insole with reinforcement and arch elevation features (R+U+) evaluated by Cheng et al. [36] significantly increased pressure in the medial midfoot and reduced pressure in the hindfoot, whereas the non-reinforced features (R−U−) showed patterns similar to the control condition, confirming lower biomechanical support. This finding indicates that the insole structure and reinforcement design directly affect plantar pressure distribution and arch stabilization. However, a study by Zuñiga et al. [55], which focused on individuals with diabetes, used two types of polymers—thermoplastic polyether-polyurethane and thermoplastic polyurethane polyester-based polymer—and reported no significant difference in average peak pressure distribution between 3D-printed insoles and standard insoles. This contradiction in the results may arise from both the subject group (people with diabetes) and the materials used. The lack of significant difference in pressure distribution in the study with diabetic patients suggests that diabetic conditions may influence the performance of 3D-printed insoles, necessitating further exploration of how these insoles interact with different conditions, such as diabetes, and the role of material composition in their effectiveness.

In addition, a decrease in vertical ground reaction force (vGRF) was observed in the flexible 3D-printed insole compared to the control condition [38]. While this decrease was not statistically significant, it suggests that flexible insoles can help dampen the impact force when the foot strikes the ground, which is beneficial for reducing the axial load on the lower extremity [38]. This finding aligns with studies by Chen et al., [1] and Kim et al, [56], which noted that while several studies on insoles (including 3D-printed ones) did not show significant differences in ground reaction forces, the potential for impact reduction still exists. For example, Kim et al. [56] used Thermoplastic Polyimide (TPI) for 3D printing their insoles, but despite the material choice, the study still found no significant change in GRF, even though there was a reduction in vGRF. This highlights a contradiction in the material effects, where different 3D printing materials like TPI and TPU may not show significant differences in GRF reduction, despite both demonstrating some degree of shock absorption. The ability of flexible 3D-printed insoles to absorb shocks and distribute pressure more evenly contributes to a reduction in peak vGRF compared to conditions without insoles. The cushioning materials used in these insoles, such as soft rubber or specialized foam, are more effective at absorbing pressure than regular shoe soles, thereby reducing the load transmitted to the feet during walking or running [57], [58], [59]. Furthermore, the customizability of 3D-printed insoles allows them to be designed according to the user's specific needs, supporting targeted areas of the foot and helping to evenly distribute pressure, thereby mitigating high-pressure points that can contribute to increased vGRF [38], [60], [61].

The kinetic evaluation also included aspects of joint moments. The use of FDM-based flexible insoles showed a trend towards decreased moments at the ankle joint, reflecting improved stability and reduced workload of the ankle stabilizing muscles [39]. This is consistent with findings from several studies, such as those by Lin et al. [61], who observed that 3D-printed foot orthoses made from PLA reduced the maximum ankle evertor moment and

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significantly decreased the peak external rotator moment. However, a contradiction arises when considering the study by Lin et al. [61], where the material used was PLA, a rigid thermoplastic material. In contrast, the studies reviewed in this paper predominantly focus on flexible materials, such as TPU, which are more elastic and deformable. Despite this difference in material properties, both types of insoles (PLA and flexible materials) showed a trend towards reducing ankle joint moments. The decrease in ankle joint moment when using a flexible 3D-printed insole compared to no insole is caused by several biomechanical adjustments influenced by the insole. One of the main factors is the change in movement and force at the ankle joint. 3D insoles have been proven to reduce the maximum eversion moment by up to 35% and the external rotation moment by up to 16% compared to standard shoes without insoles [61]. This happens because the insole provides better support and helps maintain foot alignment, thereby reducing the pressure and torsion acting on the ankle joint. Additionally, 3D-printed insoles can be customized to individual needs, providing support for the foot arch and additional cushioning that enhances foot stability. With a more even distribution of forces, the body does not need to rely on large joint moments to maintain balance and propulsion while walking [39], [44].

Certain insole designs, such as those with arch support and extra cushioning, have also been proven to reduce maximum eversion position and ankle eversion moment [44]. With reduced movement in the rear foot, the foot position becomes more stable and neutral during walking, which contributes to the overall decrease in ankle joint moment. Additionally, the comfort provided by the 3D insole helps create a more natural and efficient walking pattern. Users who feel more comfortable with this insole tend to experience less compensatory movement and excessive joint moments due to discomfort or poor foot alignment [2], [39].

The biomechanical adjustments produced by this insole can also encourage a more stable and cautious walking pattern, which is associated with a lower risk of injury. This more controlled walking style leads to a reduction in ankle joint moments, as the body adapts to more stable and controlled movements [44]. Thus, the decrease in ankle joint moment observed when using 3D printed flexible insoles is primarily due to better support, stability, and comfort, which results in more efficient force distribution and reduces the need for excessive joint moments during walking [39], [44], [61].

In addition to providing better cushioning, 3D insoles also affect the way a person walks, which helps reduce impact forces. For example, insole users often show increased knee flexion when their foot first touches the ground, which helps to dampen the pressure when stepping [57]. The design of insoles equipped with arch support and heel cushioning can also help adjust the foot position to be more stable and reduce tension on the muscles and joints [45], [62]. In addition, the flexibility of the material and specialized designs, such as adjusted friction levels at the front and heel, play an important role in reducing the peak forces received by the foot. With the right combination of materials and appropriate design, 3D-printed insoles can help provide better comfort, reduce excessive pressure, and enhance protection for the user's feet [38].

Comfort Evaluation

The comfort experienced by footwear users can impact physical mobility, performance, as well as general foot-related complaints, whether in the general population, athletic groups, or in a clinical context [63]. Materials, especially in terms of shoe insole, also have a clear impact on user comfort [64].

The comfort evaluation of flexible 3D printed insole in various studies was conducted using instruments such as the Visual Analogue Scale (VAS) [27], [40], the AOFAS (American Orthopedic Foot and Ankle Society) questionnaire [11], [12], and the Likert Scale [39]. The results consistently show an increase in comfort scores after the use of flexible 3D insoles. However, it is important to note that most studies used subjective scales without a blinded control group. Therefore, the reported improvements may be influenced by participant expectation bias, as participants were aware of the intervention being tested.

Based on the results of the studies, the use of Filaflex (a TPU-based elastomer) in a 3D printed insole with a specific geometric structure can improve comfort, especially in the areas of heel cushioning, arch support, and heel cup stability, compared to the condition without an insole [27]. In addition, TPE materials used in 3D printing insoles can provide optimal flexibility while maintaining long-term shape and durability [40]. In another study, results showed that the use of 3D printed insoles made of elastic polyurethane [11] and TPU [12], when used regularly for more than 4 hours per day, resulted in a significant improvement in functional comfort. Specifically, 93% of AOFAS scores fell into the "good" to "excellent" category [12] and respondents reported decreased joint pain after continued use [11]. Meanwhile, the 3D printed insole with total contact type offered the highest comfort score compared to other designs. This is closely related to the precision of the TPU-based 3D printing, which can optimally adapt the insole surface to the plantar foot shape. On the other hand, the medial wedge and auto-scan types showed lower comfort levels, while the lowest scores were found in the no insole condition [39]. The placement of an EVA layer over the TPU sole was also reported to play a role in improving surface comfort and reducing skin irritation due to friction during use.

The use of flexible material 3D printed insoles for the treatment of flatfoot shows significant effectiveness in increasing user comfort, reducing pain, and improving foot function. One of the main advantages of this technology is that it allows for the creation of insoles that are highly customized to the anatomical and biomechanical needs of each individual. This customization results in a better fit and more optimal comfort, which is crucial for long-term use and the effectiveness of the insole [8], [12], [39]. Additionally, studies show that 3D-printed insoles are capable of distributing pressure more evenly compared to traditional prefabricated insoles, thereby enhancing user comfort [2], [51].

In addition to enhancing comfort, 3D-printed insoles are also effective in reducing pain in individuals with flat feet. Better support for the medial longitudinal arch (MLA) and more optimal foot alignment contribute to reduced pressure on the foot structures, ultimately decreasing pain levels [8], [40], [51]. Additionally, these insoles are capable of correcting biomechanical parameters such as dynamic navicular drop and rearfoot eversion angle, which are major factors in flatfoot-related pain [39], [40].

In terms of improving foot function, 3D-printed insoles provide better support for the MLA and help maintain the alignment of the rear foot, which is crucial for maintaining optimal biomechanics during daily activities [11], [39], [40]. Additionally, these insoles effectively reduce pressure in the metatarsal area and enhance support in the midfoot, contributing to better foot function and reducing the negative impact of flat feet [41], [51].

Advancements in 3D printing technology also enable the production of insoles at lower costs and faster manufacturing processes compared to conventional methods, making them accessible to more individuals [39], [65]. Additionally, the integration of advanced materials such as elastic mesh padding further enhances dynamic support and comfort, making it superior to conventional insoles (Hu et al., 2023). With these various benefits, 3D-printed insoles offer an innovative and effective solution for individuals with flat foot.

Opportunities and Challenges of Using Flexible Materials for 3D-Printed Insoles

One of the main advantages of 3D printing technology in flexible insole manufacturing is its ability to customize designs in a personalized and individualized manner. This technology enables the creation of insoles that are customized to the foot shape and plantar pressure distribution of each individual, thereby increasing their comfort and effectiveness [27], [67], [68]. Specifically, Cheng et al. [38] demonstrated that 3D-printed insoles based on

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personalized foot scans resulted in improved plantar pressure distribution and enhanced medial arch support. Similarly, Wang et al. [11] and Shaikh et al. [12] utilized scanning-based customization to produce flexible insoles that improved functional comfort and reduced joint pain, indicating that the opportunity for customization in 3D printing translates directly to measurable user benefits rather than being a general technological advantage. In addition, flexibility in the pattern and density of the infill enables the production of insoles that can specifically provide additional support or cushioning to specific areas that require it the ability to adjust the pattern and density of the infill in 3D printing enables the production of insoles that provide specific support or cushioning to areas that require it, further enhancing comfort and function [67], [68].

In terms of material efficiency and waste reduction, additive manufacturing methods reduce material wastage compared to conventional manufacturing techniques, making them a more sustainable option [67]. Flexible materials such as TPU (Thermoplastic Polyurethane) are the top choice due to their high elasticity and durability, thus providing an optimal balance between flexibility and durability of the insole [54], [67], [69]. Cheng et al. [38] and Hsu et al. [39] confirmed that TPU is not only biocompatible but also ensures biomechanical support, making it ideal for flatfoot treatment.

In terms of biomechanical performance, 3D printing-based insoles are able to distribute plantar pressure more effectively, reduce peak pressure, and potentially reduce foot pain [67], [70]. The studies consistently found that 3D printing allows the fine-tuning of flexible insole features that directly affect biomechanical outcomes, such as reducing stress on the medial arch and optimizing foot stability. Cheng et al. [36], Hsu et al. [37], Praewpipat et al. [40] observed that 3D-printed flexible insoles improved ankle dorsiflexion, increased the navicular height, reduced rearfoot eversion, and helped distribute pressure more evenly across the foot. In addition, the integration of conductive materials such as carbon nanotubes can add additional features such as pressure sensors, which are useful for gait analysis and other biomechanical applications [54], [71], [72].

Another advantage of 3D printing is the ability for 3D printing also enables rapid prototyping and production, The technology allowing for for faster iteration and adjustment of designs based on user feedback, thereby improving production efficiency and product development [27], [68]. This ability to quickly modify designs based on feedback has been noted by Cheng et al. [38] and Wang et al. [11], who found that this feature improves both the efficiency of production and product development processes. In addition, this technology supports the creation of complex structures that are difficult or even unachievable with traditional manufacturing methods [73], [74].

However, despite offering many advantages, the use of flexible materials for 3D-printed insoles still faces several challenges. One of the main obstacles is the limited types of flexible materials available for 3D printing. Finding a material that has the optimal balance between flexibility, durability, and ease of printing is still a major challenge [69], [75]. In addition, technical issues such as nozzle clogging, filament buckling, and material jamming during printing often occur with materials such as TPU, requiring careful calibration and optimal adjustment of printing parameters [69], [76].

Print quality and production consistency are also a challenge. Factors such as poor adhesion of the print bed and oscillation of the top layer of the print can cause discrepancies in the insole shape [76]. In addition, it is important to ensure that the mechanical characteristics of the molded insole, such as tensile strength and elongation before fracture, meet the required standards for effective long-term use [77]. There are also accuracy discrepancies, as reported by Hsu et al. [39], who found a difference of 0.5% between the maximum width of a real insole and a digital insole. This difference could be due to the thermal expansion of the TPU material during the printing process [39].

The integration of additional features such as sensors and conductive materials in the insole offers further benefits, but also adds complexity to the manufacturing process [54], [71]. One of the main challenges is to ensure that the additional components do not reduce the flexibility and comfort of the insole, so that it remains comfortable for daily use [54], [72].

In addition to the technical challenges, clinical validation of 3D printing-based insoles is still limited. More clinical research is needed to verify their effectiveness in various medical applications, such as the treatment of flatfoot or the reduction of knee pain during running [11], [27]. In addition, large-scale clinical trials are needed to establish standardized protocols and ensure that 3D printing-based insoles can be widely used in medical applications with a high degree of reliability [11], [68].

Summary of Evidence and Conclusions

The synthesis of evidence from the reviewed studies clearly addresses the research questions posed at the beginning of the manuscript. In terms of RQ1, the findings indicate that flexible 3D-printed insoles significantly improve plantar pressure distribution, reduce peak pressure, and enhance overall foot stability, which are all critical factors in treating flatfoot. The studies consistently reported that these insoles also contribute to increased navicular height, reduced rearfoot eversion, and improved ankle dorsiflexion, all of which are crucial biomechanical adjustments for those with flatfoot. Additionally, the use of personalized foot scans for customization further optimized these biomechanical outcomes. Regarding RQ2, the evidence shows that these insoles notably enhance comfort. Customization, based on individual foot scans, significantly improves functional comfort. Insoles made with TPU and TPE show better adaptability to foot contours, thereby reducing pressure points that can cause discomfort. Evaluation using VAS (Visual Analogue Scale), AOFAS (American Orthopedic Foot and Ankle Society Scores), and the Likert scale showed a significant improvement in user comfort, particularly in stability, arch support, and insole durability during daily use. Furthermore, the flexibility in adjusting the pattern and density of the infill ensures that the insoles provide specific support or cushioning to areas requiring additional attention, further improving overall comfort. This combined evidence highlights that 3D-printed insoles not only offer substantial biomechanical benefits but also enhance user comfort, thus offering a promising solution for flatfoot treatment and related conditions.

CONCLUSION

The aim of this systematic review was to assess the biomechanical impact and the perceived comfort of 3D printed FDM insoles made of flexible materials for flatfoot treatment. The findings suggest that these insoles may improve key biomechanical parameters such as the height of the medial arch, the increase in the dorsiflexion of the ankle, the reduction of the eversion of the ankle and the optimization of the distribution of the plantar pressure, which can help to reduce pain, improve stability and improve alignment. Flexible materials such as TPU and TPE allow insoles to conform to the leg contours, providing greater comfort and reducing pressure points, and previous studies have shown that insoles have adequate arch support and durability for everyday use, which contributes to user satisfaction. Despite these benefits, the evidence is still insufficient to support similar results in larger populations. Although 3D printing offers advantages such as cost-efficiency and customization, challenges remain, such as limited material choices, inconsistent print quality and machine-related problems, which need to be addressed before it can be widely used in the clinical setting. Overall, flexible insoles printed with FDM have a strong potential as an alternative to traditional orthotics, but further research - including large-scale randomised trials and comparative studies with printing technologies (FDM, DLP, SLA, SLS) - is needed to confirm clinical results and optimise performance. The limitations of this review include the reliance on a single database (Scopus), the small size of the sample in most of the studies and the inconsistent methods of measurement of comfort and biomechanical parameters, which have an impact on the generality and comparability of the data. However, the overall evidence shows that 3D printed flexible

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insoles are effective as a supportive footwear for flat feet and offer promising improvements in comfort and leg motion.

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CONFLICT OF INTEREST

The authors declare no competing interests.

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DECLARATIONS HUMAN AND ANIMAL RIGHTS

This article does not contain any studies with human or animal subjects performed by any of the authors.

DATA AVAILABILITY STATEMENT

Due to privacy restrictions, the data are not publicly available. De-identified data may be available from the corresponding author upon reasonable request.

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