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Investigating the Effect of Semi-Hard Medical Insoles Made with CAD-CAM Technology on Balance and Pressure Caused by Flexible Flatfoot in the Ages of 12 to 40 Years: Systematic Review

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Review Article

Abstract

Introduction: Flexible flatfoot causes pain in higher joints and disturbs the pressure distribution of soles in affected people. In this study, we aimed to determine the effect of three-dimensional (3D)-printed insoles and computer-aided design/computer-aided manufacturing (CAD/CAM) in reducing pressure and pain in people with flexible flatfoot.

Materials and Methods: The present study was designed as a systematic review based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. An extensive search was conducted in the most important databases including PubMed, Web of Science, Embase, Cochrane, and Scopus. The methodological quality of the included studies was evaluated through Downs and Black's checklist. A form was also designed to extract the most important findings of the studies based on the research objectives, and finally the results of the studies were evaluated.

Results: In the electronic search, 19 articles that met the inclusion criteria were published between 2003 and 2022. Insoles that used 3D-design technology and CAD/CAM might have a positive effect on pain and function and distribution of foot pressure in patients with flat feet during the period of patient investigation. But there was no reliable evidence due to the examination of different outcomes and the small number of studies in this regard.

Conclusion: Although the use of 3D insoles and CAD/CAM played a role in reducing pressure and pain and increasing the comfort of patients with flexible flatfoot, the evidence in this field is insufficient and requires more studies.

Keywords: Foot orthosis; Flatfoot; Pes planus; CAD/CAM; 3D-printed insole

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Introduction

The human foot undergoes more structural changes than any other body part (1). One of the foot's most important and variable structural features is the height of the longitudinal-internal arch when bearing weight (1). Foot deformities may occur due to external factors, certain foot conditions, or diseases. Although not always the case, foot deformities can cause pain and changes in walking patterns (2). In individuals with fallen arches, the longitudinal-internal arch of the foot is flatter than normal. When standing and walking, most of the foot, from the heel to the instep, comes into contact with the ground. Fallen arches can cause pain after a few years, mainly when the person puts weight on them. The possible causes of fallen arches include weakness of the foot muscles, abnormal pressure on the foot, and joint inflammation (2). One common treatment for reducing complications caused by foot lesions is insoles. These insoles help to return the foot's arch to its normal state and reduce tissue stress during use (3, 4). Additionally, they help to reduce muscle activity that stabilizes or controls the axis of rotation in the foot (5). Different types of insoles are available with arch support, including customized insoles, prefabricated arch support insoles, and insoles made with

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computer-aided design/computer-aided manufacturing (CAD/CAM) technology. A study by Daryaber et al. showed that using a medial wedge on three-dimensional (3D)-printed insoles could benefit the biomechanics of lower limb gait in people with flat feet. However, they found no significant difference between 3D-printed and other insoles, and no substantiated evidence supports this claim (6). In some studies, the specific design of CAD/CAM foot orthoses did not make a big difference in the plantar pressure distribution in the sample. However, further research is needed to determine whether this relates to different scanning systems or design software (7). Insoles can be an effective treatment for reducing complications caused by foot lesions. Several studies have raised doubts about the efficacy of foot orthoses in treating children's flexible soles, and it is necessary to conduct more studies to investigate methodological limitations (8). Previous review studies could not achieve a clear picture of the use of 3D insoles in relieving patients' symptoms due to the lack of available evidence (9). Additionally, past studies were conducted on older methods of making medical insoles and did not investigate newer techniques, like insoles made with CAD/CAM technology (9). These materials suggest the need for more recent studies to draw conclusions and compare studies in the form of a review. Therefore, a systematic review is needed to investigate the effect of semi-hard medical insoles with CAD/CAM technology on the smoothness of flexible soles in 12-40-year-olds while considering the intended outcomes like balance and pressure, effectiveness of different insoles, and whether they provide significant benefits over other treatments.

Materials and Methods

This is a systematic review study, which is a type of secondary research method. The study included articles that were published 12-40 years ago and were identified through a systematic review process. The articles were written in English and were sourced from various databases such as Cochrane, Web of Science, Scopus, PubMed, and Embase. Two researchers conducted the information search strategy using a specific search strategy:

(“flat foot” OR “flat feet” OR “flexible flat foot” OR “flexible flat feet” OR “acquired adult flat foot” OR “acquired adult flat foot” OR “acquired adult flat feet” OR “pes planus” OR “pes plano valgus” OR “acquired flatfoot” OR “foot deformities” OR “acquired adult flatfoot deformity”) AND (“semi-rigid insole” OR “semirigid insole” OR “semi-rigid insole" OR “foot orthotic device” OR “foot arch support” OR "computer-aided design” OR “computer-aided manufacture” OR “CAD/CAM” OR “CAD/CAM” OR “3D printed insole*” OR “computer numerical control insole*” OR “CNC insole” OR “foot orthoses” OR “insole” OR “arch support”) AND (“balance” OR “pressure” OR “plantar pressure” OR “foot plantar pressure” OR “plantar pressure distribution” OR “pressure distribution insole” OR “pressure distribution foot” OR “pressure distribution feet”).

The review articles, including clinical trials and case studies, were all related. We made sure to retrieve comprehensive articles, but we did not spend too much time searching for them. We excluded articles that did not have access to full text, were unrelated to the study objective, were conducted on CAD/CAM in other diseases not related to flat feet, and were published in non-English language. The study was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) design.

Two researchers reviewed the articles independently, and disagreements were resolved by discussing them with a third researcher. We excluded articles that did not have enough data for the study. The quality of the included studies was evaluated using the modified version of Downs and Black's checklist (10, 11) which contains 17 questions (Table 1). Based on Downs and Black's list, the score that could be obtained was 17. A score of 7 is considered poor quality, 8 to 13 is relatively good, and 14 to 17 is considered good.

After performing the search using the specified words, we examined the moderator responsible for the abstract of the articles. We removed overlaps and checked the title and abstract for relevance. Then, we reviewed and verified the full text of the articles and extracted and recorded the information from the articles in a particular form.

Results

A total of 861 studies were found in the initial electronic search, which were then entered into Endnote X9 software (EndNote 20.2.1 for Windows, released 11.30.2021, Clarivate, Chandler, AZ, USA). Out of these, 515 studies were not relevant to the type of disease, measured parameter, or study review, and therefore, were removed. Additional 234 articles were excluded from the study due to duplicate titles. The remaining 112 articles were then screened based on their relevance to the study topic, by examining their titles and abstracts. Out of these, 83 articles were excluded. The remaining 29 articles underwent further screening.

Table 1. Downs and Black's checklist (Part I)

Quality items	Report								External validity
	Q1	Q2	Q3	Q4	Q6	Q7	Q9	Q10	Q11
	Hypothesis/aim	Main outcomes in meth/intro	Inclusion/exclusion criteria	Description of interventions	Main findings	Random variability	Lost to follow-up	Actual probability values	Representative of the entire population
Telfer et al. (23)	1	1	1	1	1	1	1	1	0
Khodaei et al. (7)	1	1	1	1	1	1	1	1	0
Kim et al. (34)	1	1	1	1	1	0	1	0	0
Joo (24)	1	1	1	1	1	0	1	0	0
De Melo Lopes Martinho Malaquias et al. (25)	1	1	1	1	1	1	1	0	0
Xu et al. (26)	1	1	1	1	1	1	1	0	0
Cherni et al. (27)	1	1	1	1	1	1	1	1	0
Ho et al. (28)	1	1	1	1	1	1	1	1	0
Hu et al. (29)	1	1	1	1	1	1	1	1	0
Cheng et al. (30)	1	1	1	1	1	1	1	1	0
Stolwijk et al. (31)	1	1	1	1	1	1	1	1	0
Su et al. (32)	1	1	1	1	1	1	1	0	0
Wang et al. (33)	1	1	1	1	1	0	1	0	0
Mo et al. (2)	1	1	1	1	1	1	1	0	0
Yosra (11)	1	1	1	1	1	1	1	0	0
Jandova and Mendricky (22)	1	1	1	1	1	1	1	1	0

Table 1. Downs and Black's checklist (Part II)

Quality items	Internal validity-bias				Internal validity-confounding			Power	Total
	Q14	Q15	Q18	Q20	Q22	Q23	Q26	Q27	17 possible
	Blind study subjects	Blind those measuring	Statistical tests appropriated	Outcome measures used accurate	Same period of time	Random allocation	Losses of patients to follow-up	Estimate of statistical power	-
Telfer et al.(23)	1	1	1	1	0	0	1	1	14
Khodaei et al.(7)	1	1	1	1	0	0	1	0	13
Kim et al.(34)	0	0	0	1	0	0	1	0	8
Joo (24)	0	0	1	1	0	0	1	0	9
De Melo Lopes Martinho Malaquias et al.(25)	0	0	1	1	0	0	1	0	10
Xu et al. (26)	0	0	1	1	0	0	1	0	10
Cherni et al. (27)	1	1	1	1	0	0	1	0	13
Ho et al. (28)	1	1	1	1	1	0	1	0	14
Hu et al. (29)	1	0	1	1	1	0	1	0	13
Cheng et al. (30)	0	0	1	1	0	0	1	0	11
Stolwijk et al. (31)	1	1	1	1	1	0	1	0	14
Su et al. (32)	0	0	1	1	0	0	1	0	10
Wang et al. (33)	0	0	1	1	0	0	1	0	8
Mo et al. (2)	0	0	1	1	1	0	1	0	10
Yosra (11)	0	0	1	1	1	0	1	0	11
Jandova and Mendricky (22)	0	0	1	1	1	0	1	0	12

Three of these studies were published in non-English languages, two articles were excluded due to the author's lack of response, three studies did not use CAD/CAM technology, and one study did not examine the patient's pressure and balance. Four studies were excluded as they analyzed other foot abnormalities such as diabetes, plantar fasciitis, high arch, and clubfoot or focused on studies on healthy people (Figure 1).

After conducting the study, 16 articles were chosen for the final review which are listed in table 2 (22-25, 7-11). Clinical trials and quasi-experimental studies were conducted in England, China, Iran, Austria, the Netherlands, Turkey, Hong Kong, and the Czech Republic. The articles included in this systematic review were published between 2003 and 2022.

In figure 2, the research results are displayed as a percentage.

Discussion

The investigations conducted in this study reveal that patients who use insoles made with CAD/CAM technology feel much more comfortable (22, 24-26). This technology also helps to increase balance and stability while walking. The pain reduction experienced by individuals using insoles can be attributed to the redistribution of foot pressure while walking or running. This is due to the fact that the type of insole is designed to apply the medial wedge and navicular pad. However, it is important to note that the results of these studies should not be generalized, as some studies did not observe a difference between using this type of insole and prefabricated or traditional insoles (7, 27). It is important to note that the number of studies conducted with entry criteria in this field is small. Therefore, 75% of the studies showed that wearing insoles made with CAD/CAM technology was potentially more helpful than prefabricated insoles (24, 25, 28, 29-34). Meanwhile, 25% of articles showed no difference in the effect of computerized and traditional insoles (7, 27, 33).

Several studies have examined the effects of different types of insoles on the biomechanics of walking in people with flat feet (9). One study found that 3D-printed insoles with a medial wedge could improve lower limb biomechanics (35). In contrast, another study found that 3D-printed insoles could improve comfort and foot function in people with flat feet (35). A study comparing different types of custom insoles in people with painful, flexible, flat feet found that two types of customized and prefabricated insoles reduced pain compared to ready-made insoles (36).

Another study compared the parameters of three groups of people with flat feet while running with and without insoles. It was found that those using insoles made with traditional molding or 3D printing had better ankle joint control than those without insoles.

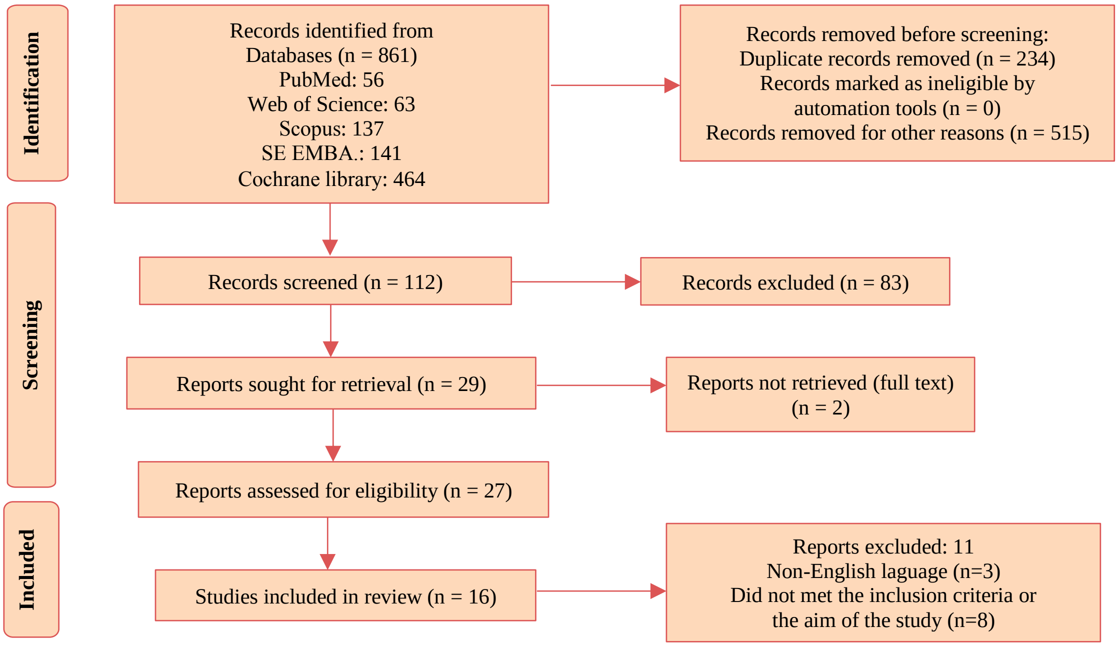

Figure 1. Screening of studies based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart (23)

Table 2. List of articles found from 2003 to 2022

First author	Study place	Study type	Average Age	Male and female sample	Diagnostic method	Sole type used	3d printing system	Follow-up	Consequences
Talfer (23)	England	Quasi-experimental	29.9	12 patients	FPI, RCSP	Custom 3D printed insoles with external back support from 6° lateral to 10° medial	RapMan; Bits from Bytes, Clevedon, UK	2 weeks	Although taking EMG did not significantly affect foot muscle activity, it caused a normal distribution of plantar pressure.
Khodaei (7)	Iran	Quasi-experimental	22.89	19 (2 men, 17 women)	FPI	CNC insole made of EVA material and prefabricated foot insole	TekScan MatScan® system	Immediately	Both CAD/CAM and prefabricated insoles distribute pressure with a pattern in patients with flexible, flat feet. Special CAD/CAM insole design cannot significantly affect plantar pressure distribution.
Hu (29)	Austria	Quasi-experimental	Not reported	Not reported	Normalized navicular height truncated	Comparison of prefabricated insoles and insoles made by 3D printer	J750 PolyJet 3D printer	2 weeks	The use of insoles made with a 3D printer increased the balance in walking and provided better support for the internal longitudinal arch in order to better match the soles of the feet and, as a result, brought comfort to the patient.
Kim (34)	South Korea	Quasi-experimental	22.87	15 patients	Navicular drop test	Custom 3D printed insoles	Cubicon® 3DP-110F, HyVision, Korea	Not reported	Although the custom 3D printed insoles were not effective on joint angles and ground reaction forces, the former positively affected the central pressure path during the stance phase.
Joo (24)	South Korea	Quasi-experimental	22.87	15 patients	RCSP	3D printed soles, prefabricated insole	EinScan-Pro, Hustem, Korea and EinScan-Pro software, Hustem, Korea	Not reported	The customized 3D-printed insoles somewhat affected the pressure distribution of people with flat feet by changing the direction of the central pressure.
Xu (26)	China	Randomized clinical trial, single-blind	38.81	80 (40 men, 40 women)	FPI	Custom 3D printed EVA insoles, prefabricated insoles	Bodyarch X1 Printer®	8 weeks	Customized 3D-printed insoles reduced pressure on the metatarsals by distributing pressure in the midfoot area. Custom 3D printed insoles were more effective than prefabricated insoles and provided better comfort for patients with flat feet.
De Melo Lopes Martinho Malaquias (25)	England	Quasi-experimental	40.2	18 patients	Dynamic plantar pressure data	3D printed soles, sole with EVA foam	RSscan International, Belgium	Immediately	Using both types of 3D print soles and EVA in people with flat soles improved the dynamic condition of the foot and, as a result, increased the arch's height and balance. There was no significant difference between the two soles.
Cherni (27)	Canada	Quasi-experimental	37.6	19 (6 men, 13 women)	FPI	Two pairs of insoles made with a 3D printer with different degrees of hardness	Not reported	Immediately	The stiffness of the foot orthosis and the addition of posting affects the pressure on the sole during walking. The stiffness of the foot orthosis changes the plantar pressures under the midfoot area.

Table 2. List of articles found from 2003 to 2022 (continue)

First author	Study place	Study type	Average Age	Male and female sample	Diagnostic method	Sole type used	3d printing system	Follow-up	Consequences
Ho (28)	Australia	Single-blind crossover clinical trial	45.8	13 (5 men, 8 women)	FPI	3D printed insoles and traditional insoles	Commercial prefab	Immediately	In people with flat feet, using 3D printed insoles is as effective as traditional insoles in changing biomechanics and maintaining balance in the ankle joints.
Cheng (30)	China	Randomized crossover trial	20.4	10 (4 men, 6 women)	Plantar arch index and navicular drop index	Custom 3D printing	Nmotion Orthotic Lab, Knoxville, TN, USA	Immediately	The increase in pressure in the middle part of the foot was measured, which indicated the support of the longitudinal-internal arch. Also, correction of foot pronation and heel eversion was resulted.
Stolwijk (31)	Netherlands	Quasi-experimental	54.9	223 (73 men, 193 women)	Arch index	3D-printed insoles	Precision 3D limited, UK	Immediately	The designed insoles were given to all groups with different problems. The distribution of sole pressure was the same for all groups.
Su (32)	China	Case study	12	One man	Navicular drop index	3D-printed insoles	Infoot, I-Ware Laboratory Co., Ltd., Japan	Immediately	In general, the material of the sole and its design has a positive effect on correcting the smoothness of the soles of the feet, but it leads to increased pressure on the joints and ligaments.
Wang (33)	China	Quasi-experimental	26.3	50 (19 men, 31 women)	Arch index	3D-printed insoles	IFOOT-DK3, Shenzhen, Guangdong, China	3months to one year	3D printed insoles can help reduce pressure, relieve fatigue and pain, improve stability, and support foot movement.
Mo (2)	Hong Kong	Quasi-experimental	36.4	13 women	Static and dynamic measurements of the hindfoot in clinical	3D printed	IdeaMaker, Raise3D, Costa Mesa, CA, USA	Immediately	The two groups that used the insoles made with the traditional molding method and those made with a 3D printer felt more comfortable and had better ankle control than those that did not receive any orthotics. This shows that orthoses made with CAD/CAM technology can be a suitable alternative to traditional molding orthoses.
Yosra (11)	Canada	Quasi-experimental	37.6	19 (13 women, 6 men)	FPI	3D printed	Unable to determine	Immediately	The higher the degree of hardness of the sole, the greater the distribution and increase of pressure, but it did not affect the amount of muscle activity.
Jandova (22)	Czech Republic	Quasi-experimental	40.6	51 patients	FPI	3D printed, EVA	Unable to determine	Immediately	Both custom-made insoles, with the help of pressure distribution, reduced the pressure in patients with plantar deformities and brought people's satisfaction. Finally, they suggested the insoles made with 3D printers and CNC insoles to match them more with the soles of the feet.

FPI: Foot posture index; RCSP: Resting calcaneal stance position; EVA: Ethylene-vinyl acetate; EMG: Electromyography; CAD/CAM: Computer-aided design/computer-aided manufacturing; 3D: Three-dimensional; CNC: Computer numerical control

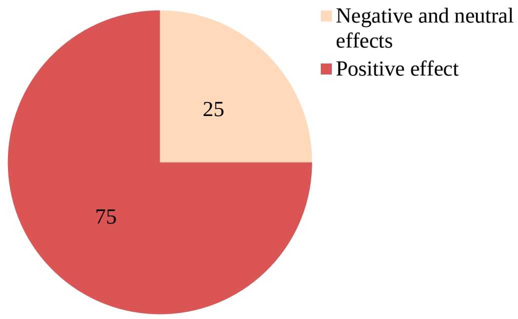

Figure 2. Percentage of positive/negative/neutral effects of using insoles made with computer-aided design/computer-aided manufacturing (CAD/CAM) technology

In yet another study, 3D-printed insoles with varying degrees of hardness were given to 19 people with flat feet, and it was found that the distribution of pressure and its amount was more significant in insoles with a higher degree of hardness (13, 37).

Finally, a study compared two types of prefabricated insoles and CAD/CAM in people with flat feet and found that the insoles made with CAD/CAM technology reduced pressure on the metatarsal bones and provided better patient comfort. This suggests that the prescription of this type of insole could benefit people with flat feet.

A study compared two types of prefabricated insoles and CAD/CAM technology in people with flat feet, with an average age of 38. The researchers found that insoles made with CAD/CAM technology reduced pressure on the metatarsal bones by distributing it evenly across the middle of the foot, unlike the prefabricated type (38). This resulted in better comfort for patients, making it worth considering the prescription of this type of insole.

Foot orthoses are a standard method for rehabilitating patients with flat feet. However, further evidence is required to establish their effectiveness in addressing the problems faced by these patients. A review conducted by Choi et al. revealed no strong evidence that using insoles over a long period improved the structural problem of flexible flat feet in children. Another review study suggested that the flatness of the child's soles improved as they grew. In contrast, several studies have shown insoles' positive impact on the soles' flatness in terms of structural improvement (35). The type of treatment and structural correction required for the foot can depend on various factors, such as the patient's characteristics, activity type, and personal preferences. For instance, in Cheong's study, three interventions were given to patients, including medical insoles, leggings, and sports bras, and all three were effective in controlling the pronation and eversion of the foot (29, 39).

Moreover, a review study of flatfeet among children revealed that insoles caused the heel to deviate and the foot to rotate outwards. However, there was still insufficient evidence in this field (40).

According to some studies, using insoles may initially increase pressure in the middle area of the foot, indicating support for the longitudinal-internal arch and correction of foot pronation (41). However, long-term use of insoles can decrease pressure, improve stability (34), and support foot movement, thereby improving balance (42, 43).

Studies comparing medical insoles designed with CAD/CAM technology to traditional methods found no difference in the impact of these insoles on muscle activity. However, they differed in biomechanical changes and maintaining balance in the ankle joint (13, 33, 43).

Several studies have shown significant differences between various types of insoles. Those who used the insole made with a 3D printer observed better control and balance in the personalized ankle (2, 27). Computerized insoles are also more compatible with an individual's foot and more accurate in measurement than traditional insoles (31).

Insoles are commonly used to distribute plantar pressure and increase patient comfort. Recent studies have shown that customized insoles created with 3D printers and computer numerical control (CNC) machines are more effective than prefabricated ones, leading to higher patient satisfaction (28). For instance, studies have demonstrated (25, 39, 45) that insole computers reduce pressure on the metatarsal bones and distribute it evenly across the feet, resulting in structural modification of the soles of the feet, increased stability of the ankle joint, and improved balance (27). This makes insole customization an effective treatment option that can be tailored to meet each patient's individual needs.

According to the studies, Stolwijk et al.'s (31) research involving 223 participants is more reliable than Ho et al.'s study (28), where the number of patients was not reported. Stolwijk et al.'s study found that computer-designed insoles had better pressure distribution than traditional ones.

Designing and manufacturing orthoses and prostheses using CAD/CAM technology is a new and innovative method that has caught the world's attention, including developing countries. This technology has been applied to all types of designing and manufacturing of devices, except for insoles. However, it has been successful in developing various spine braces that are lighter and thinner, providing more comfort to patients (46). The limitations of this study include the methodological quality of studies and the heterogeneity in examining study outcomes. Other limitations include sample size, sampling techniques, diagnostic criteria, treatment methods, intervention implementation and related parameters, and the lack of comprehensive evaluation measures. Additionally, maintaining balance for people is directly related to the physical condition and severity of problems of patients with flat feet (47).

Despite the advancements in insoles made with CAD/CAM technology, some problems still exist for people with flat feet. However, considering the effectiveness of this technology compared to other methods, it can be suggested that health policymakers introduce it to clinics to witness a significant improvement in clinical examinations and insole prescriptions. Moreover, with the expansion of this technology, more people can be trained and employed as experts in designing and manufacturing these insoles.

These limitations make it challenging to evaluate patients. Although the results of this study were weak due to examining different outcomes and a small number of studies, some studies showed that medical insoles made with CAD/CAM technology might positively increase balance and reduce pain, improve biomechanical performance and distribution of foot pressure, and generally improve the comfort of patients. However, there was insufficient evidence to compare insoles made with CAD/CAM technology to traditional insoles in different walking or running modes. Therefore, more studies are needed to obtain more substantial evidence of the effects of medical insoles made with CAD/CAM technology on flexible flat soles.

Limitations

It should be noted that the present study has some limitations. Firstly, due to the heterogeneity in examining the study outcomes and the methodological quality of the studies, the results should be interpreted with caution. Sample size and sampling techniques, diagnostic criteria, treatment methods, implementation of the intervention and related parameters, along with the lack of comprehensive standards in evaluating outcomes can be considered as other limitations. Furthermore, measuring pain is a subjective concept, making it challenging to check and confirm as it relates to people's personality and cultural characteristics. Additionally, maintaining a balanced position for people with flat feet is directly linked to their physical condition and the severity of their problems, making it difficult to evaluate them. Finally, it was impossible to compare the results of this study with similar cases as no similar studies have been conducted in this field.

Recommendations

It is recommended that the insole design should be tailored to patients' conditions using current methods such as CAD/CAM technology. Although research in this field is lacking, it is evident that the design and use of these orthoses can improve some problems associated with flat feet. In the future, more research should be conducted, including clinical and prospective studies, for a more detailed investigation and reliable conclusion.

Conclusion

This study's weak results were obtained due to examining different outcomes and the small number of studies. However, common results in some studies showed that medical insoles made with CAD/CAM technology might positively increase balance and reduce pain, improve biomechanical performance and foot pressure distribution, and improve overall patient comfort. There was insufficient evidence to draw a conclusion comparing insoles made with CAD/CAM technology to traditional insoles in different walking or running modes. Therefore, more studies are needed to obtain more substantial evidence of the effects of medical insoles made with CAD/CAM technology on flexible flat soles.

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Maintaining the integrity of the study process from the beginning to the publication and responding to the referees' comments: Elahe Heidari, Shahin Mojiri, Tahmoures Tahmasbi

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Conflict of Interest

The authors have no conflict of interest. Mr. Tahmoures Tahmasbi did not receive a budget for the basic studies related to this article from Isfahan University of Medical Sciences, Isfahan, Iran, and is working as a faculty member of the Department of Orthosis and Prosthetics in this university. He is a master of orthotics and a doctor of medical information in the faculties of rehabilitation and management in Isfahan University of Medical Sciences.

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