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Comparison of Foot Pressure Distribution Using Two Types of Medical Insoles Based on Location in Children with Flexible Flat Foot: A Quasi-Experimental Study

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Original Article

Abstract

Introduction: Medical insoles play an important role in correcting the biomechanical characteristics of the foot in people with flat foot. The design and construction of the insole determines how it affects the foot. The aim of this study was to compare the effect of two types of semi-custom insole and custom molded insole made based on three-dimensional scanning technology on the distribution of surface and pressure in different areas of the sole of the foot.

Materials and Methods: This quasi-experimental study was performed on 16 children with flat foot at the Musculoskeletal Research Center, Isfahan University of Medical Sciences, Isfahan, Iran. Participants were selected by simple non-probability method and randomly divided into two equal groups for intervention with semi-custom insoles and insoles made based on foot scans. The area of the parts involved in foot sole pressure and the size of the foot sole pressure and its location were measured before the intervention, immediately, and 6 weeks after continuous use of the insoles. Shapiro-Wilk test was used to examine the data distribution and two-way analysis of variance (ANOVA) was used for data analysis.

Results: Both types of insoles showed the maximum pressure in the whole sole of the foot after 6 weeks ($P = 0.04$) and the maximum pressure in the middle of the sole of the foot increased significantly for both types of insoles, while a significant decrease was observed in the front sole of the foot ($P = 0.07$). The results also showed that the use of custom insoles in comparison with semi-custom insoles did not lead to a significant difference in the average of the maximum pressure applied to the front of the foot sole ($P = 0.63$).

Conclusion: Although both custom insoles using Computer-aided design-Computer-aided manufacturing (CAD-CAM) and semi-custom insoles were effective in biomechanical effects such as pressure on the soles of the feet in children with flat feet, the custom insole was more effective. Since it is necessary to choose an advanced, uniform, and fixed method for designing and manufacturing medical insoles for children with flat feet, it is recommended that this study be performed with the help of scanners or other different and related design software.

Keywords: Insole; Flexible flatfoot; Plantar foot pressure; Scan

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Introduction

It is common for children to experience foot problems, with flat feet being a common deformity affecting around 30% of children (1). A lower-than-normal height of the internal longitudinal arch characterizes this condition (2-6). There are two types of flat feet: flexible and non-flexible. Flexible flat feet are identified when the plantar arch straightens after applying weight and returns to its previous state after removing the weight. This type of flat foot is often accompanied by external rotation of the heel (7, 8). In

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contrast, non-flexible flat feet affect about 1% of the population and are identified when the height of the arch does not change when no weight is applied compared to when weight is used (5, 9). It should be noted that the flexible type is more common, accounting for 48% to 77.9% of children with flat feet (10, 11).

Flat feet can take many forms in children, ranging from flexible to inflexible, progressive to non-progressive. To diagnose this condition, various methods are used, including checking the arch of the foot with and without weight bearing, measuring the angle of the rear part of the foot, examining the position of the heel, measuring the height of the navicular to the ground, and evaluating the shape of the arch (5, 7). Once the cause of flat feet is identified, effective treatment can be provided. It is important to note that the natural and integrated plantar pressure distribution is a biomechanical principle that should be considered when prescribing insoles. Flexible soles in children can lead to disorders such as abnormal plantar pressure distribution, abnormal walking, poor balance, and impaired motor function and body activity (5, 12, 13). Therefore, orthopedic treatment is necessary to solve the problem. Since most of these symptoms continue until old age, preparing a detailed treatment plan for this condition from childhood is essential. Doing so can initiate therapeutic intervention promptly to ensure the best possible outcome (5, 14).

Several non-surgical interventions are available for people with flat feet, including modifying activities, weight loss, exercise therapy, plastering, leg orthoses, and stretching exercises (5, 10, 11). Foot orthoses are also often recommended for flexible flat feet (6, 15, 16), which can be categorized into semi-custom and custom. Semi-custom orthoses have standard shape and form, while specialized orthoses are designed and manufactured by specialist orthoses manufacturers by molding or scanning the individual's foot in specialized clinics (3).

Since the pressure pattern in the plantar surface of people with flat feet is significantly different from that of healthy people, measuring the plantar pressure with a standard device in various positions with and without insoles is essential. This helps monitor the amount and area of pressure and analyze variables like pain and comfort. Foot pressure provides valuable information about the foot's function, and it is necessary to evaluate it for better treatment (2, 17, 18).

One of the latest computer-aided design (CAD) and manufacturing methods is the CAD-computer-aided manufacturing (CAD-CAM) system. This system comprises a three-dimensional (3D) scanner, design software, and a 3D printer. Various design software, like Meshmixer, Rhino, and Delcam, makes creating 3D models easy and precise. With the rise in technology, especially in computer design, using CAD-CAM systems has become essential in the healthcare industry, particularly in designing insoles for feet. Researchers compared the impact of the CAD-CAM method on foot pressure distribution with a semi-customized insole and concluded that both orthoses could decrease the pressure under the heel and metatarsal area (17). However, some studies have shown no significant difference in pressure distribution by the CAD-CAM design system (6).

The impact of various insole types on the amount and location of plantar pressure is not yet proven. However, using 3D design systems is incredibly useful in determining pressure distribution. Despite this, no research has been conducted regarding creating and implementing medical insoles using 3D scanners to distribute foot pressure in children with flat feet. Consequently, this study aimed to analyze and compare two types of semi-customized insoles produced using the CAD-CAM method in children with flexible flat feet.

Materials and Methods

This study utilized a quasi-experimental before-and-after design involving 16 children divided into two parallel groups. The sampling was conducted on an accessible basis from individuals referred to orthotics and prosthetics centers, both private and public, in Isfahan City, Iran, in 2019, as well as from the Musculoskeletal Research Center of Isfahan University of Medical Sciences. The insoles selected for the study were made from Plastazote foam. Inclusion criteria comprised children aged between 7-11 years, with flatness in the soles of their feet [based on the Foot Posture Index (FPI) of +9], not currently using insoles, and not having used foot orthosis for at least six months before the test. Additionally, the children needed a complete range of motion (ROM), normal muscle strength, no difference in the length of their lower limbs, and no history of trauma, dislocation, fracture, or surgery in the lower limb. Exclusion criteria included individuals with foot supination, genu varum of the knee, congenital structural deformity, neuromuscular problems (such as cerebral palsy, polio, and spina bifida), and those not regularly and daily wearing insoles (control was done through regular phone calls).

The first step was to complete the personal information questionnaire after obtaining written consent from the patients and their families. Next, the dynamic pressure test was performed using the foot pressure scanning device (Paya Fanavaran Ferdowsi Co., no. 22.1., Mashhad, Iran, ISO 13485:2016) while explaining the procedure to the participant. This test was performed before the intervention, and the participant was asked to walk slowly toward the screen at a distance of two meters from the device center in the research hall. The participant had already practiced the test multiple times before the final examination. The person was required to pass through the screen, ensuring their standing foot was in the center for correct and complete registration. The pressure test was performed dynamically three times for each person with the right foot and three times with the left foot. After each test, the examiner recorded the plantar pressure information in the system (19).

Using the FPI, the researcher checked the flatness of each person's foot in a standing position. This involved a detailed examination and observation of the foot. The FPI has six views to evaluate the foot in different planes. The six views are the posterior view for Achilles alignment, posterior view for outward and inward deviation of the toes, palpation of the talus anteriorly, internal and external view to check the concavity under the ankles, interior view for the medial longitudinal arch, and internal and external view for examining the concavity above the ankles. Each parameter assigns a score from +2 to -2, and the total score of this checklist is reported as a numerical index between +12 and -12. A positive numerical index indicates a foot-prone posture (8).

The evaluation and measurements were conducted by recording device output values. These values included determining the plantar pressure in different parts of the foot (forefoot, midfoot, hindfoot) before and after using insoles. The measurements were taken once without insoles, immediately after inserting insoles, and six weeks after using insoles. The participants were instructed to use insoles for at least 4 hours a day in their regular shoes and daily activities without removing them from the shoes. The data were tested for normal distribution using the Shapiro-Wilk test and then analyzed using a two-way analysis of variance (ANOVA) test to compare the average differences of dependent variables between two parallel groups. The data were analyzed using the SPSS software (version 22, IBM Corporation, Armonk, NY, USA). Repeated data analysis was performed based on intention-to-treat (ITT) analysis, and statistical significance was set at less than 0.05.

Results

Table 1 compares demographic characteristics between two types of insoles - customized and semi-customized - in children with flexible flat feet. The study found no significant difference between the two types of insoles regarding the demographic characteristics of children with flexible flat feet.

The comparison of the average maximum pressure on the plantar feet (kg/cm^2) before, after, and six weeks after using each of the two types of soles is shown in table 2.

Six weeks after using insoles, there was not a significant difference in the average maximum pressure applied to the midfoot between the participants (P = 0.370). However, the study found that customized insoles increased the average maximum pressure applied to the midfoot compared to semi-customized ones (P = 0.020). Moreover, there was not a significant difference in the maximum pressure applied to the hindfoot in both groups after six weeks of insole use (P = 0.460). Based on the findings, using customized insoles did not significantly impact the average maximum pressure on the hindfoot compared to semi-customized ones (P = 0.190) (Table 2).

The average maximum pressure applied to the plantar foot after using the insole is shown in figure 1.

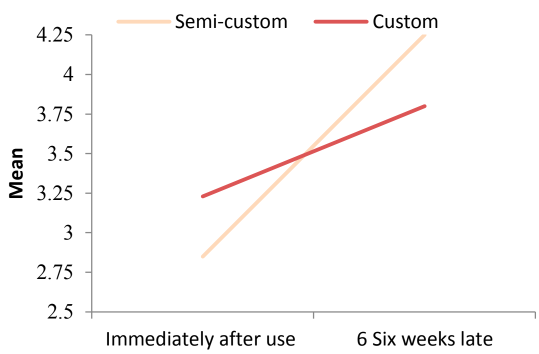

Figure 1. Average maximum pressure applied to the plantar foot after using insoles

Table 1. Descriptive statistics of contextual variables

Variable	Semi-custom insoles (mean ± SD)	Custom insoles (mean ± SD)	P-value
Age (year)	8.12 ± 1.64	9.00 ± 1.60	0.280
Weight (kg)	40.62 ± 15.95	35.87 ± 6.59	0.450
Height (cm)	120.75 ± 33.14	99.12 ± 37.06	0.240

SD: Standard deviation

Table 2. comparison of the average maximum pressure on the plantar feet (kg/cm2) before, after, and six weeks after using each of the two types of soles

Maximum pressure mean	Group	Before use	Immediately after use	Six weeks later	P value				
					Time comparison	Immediately after compared to before	Immediately after compared to six weeks later	Six weeks later compared to before	Time of use × type of insole
The plantar foot	Semi-custom	2.67 ± 1.50	2.87 ± 1.40	2.20 ± 4.26	0.040	0.220	0.005*	0.230	0.400
	Custom	3.11 ± 1.80	3.21 ± 1.50	3.81 ± 2.10	0.040	0.210	0.240	0.190	0.410
P value comparing two insoles					0.230				
Midfoot	Semi-custom	0.60 ± 0.40	0.60 ± 0.40	0.57 ± 0.33	0.370	0.240	0.820	0.250	0.280
	Custom	0.80 ± 0.82	0.80 ± 0.82	1.12 ± 0.83	0.370	0.220	0.250	0.250	0.270
P value comparing two insoles					0.250				
Fore foot	Semi-custom	2.34 ± 1.56	2.34 ± 1.56	3.87 ± 2.50	0.700	0.035	0.001*	0.030	0.210
	Custom	2.72 ± 1.31	2.72 ± 1.31	3.01 ± 2.29	0.700	0.410	0.500	0.230	0.200
P value comparing two insoles					0.030*				
Hind foot	Semi-custom	2.20 ± 1.35	2.34 ± 1.48	3.00 ± 0.57	0.460	0.140	0.700	0.150	0.270
	Custom	2.18 ± 1.20	2.31 ± 1.29	3.01 ± 2.29	0.460	0.110	0.500	0.130	0.200
P value comparing two insoles					0.150				

*$P < 0.05$

Data are presented as mean ± standard deviation (SD)

After six weeks of using insoles, there was no significant difference in the average pressure distribution level in the plantar foot of both groups, as shown in figure 2 (P = 0.810).

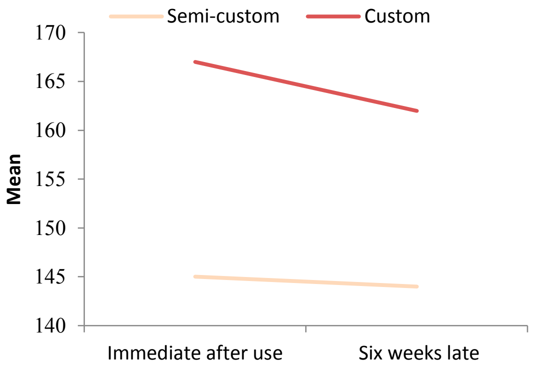

Figure 2. Average surface, including the plantar of the foot, after using insoles

The study found that using customized insoles did not significantly impact the average pressure distribution level throughout the plantar foot compared to semi-customized insoles (P = 0.120). Additionally, there was no significant difference in the average pressure distribution level in the forefoot between the two groups six weeks after using the insoles (P = 0.850). However, custom insoles significantly decreased the average pressure distribution level in the forefoot compared to semi-customized insoles (P = 0.030).

Discussion

This study aimed to compare the effects of customized and semi-customized insoles on the biomechanical indices of children's feet with flexible, flat feet. Insoles are used to increase the contact surface and support the arch, which helps distribute the load across different positions and areas of the sole. When the feet are not functioning correctly, the plantar pressure distribution of weight can be abnormal, leading to unsafe walking. Previous studies have reported abnormal pressure distribution on the plantar surface of patients with flat feet (20, 21). Research has shown that custom insoles result in different plantar pressure distribution than semi-custom insoles (22, 23).

However, this study found no significant difference between the two types of insoles. In Khodaei et al.'s study, customized insoles increased the pressure under the external toe area (17). In contrast, both insoles increased the pressure and surface area in the medial part of the foot. This study also found an increase in midfoot pressure in the customized insole, consistent with Khodaei et al.'s research. However, their customized insoles were designed using only a two-dimensional (2D) scanner, while this study used a pressure scanner inside the shoe to measure plantar pressure.

Khodaei et al.'s research found that using a pair of semi-custom and custom CAD-CAM insoles helped reduce pressure under the second to fifth metatarsals and the heel area (17). The results of this study were similar to Khodaei et al.'s research, but this change was not significant in the present study. This could be due to the type of scanner used in this study, which was only 2D. Two insoles increased the pressure in the inner part of the midfoot, but the customized insole had higher midfoot pressure, consistent with Khodaei et al.'s research. However, the change in the level of inclusion in this area was insignificant.

In the intra-group comparison, the contact areas of the intervention and control groups in the sixth week were more than the immediate intervention. One of the main mechanisms of plantar impaction is the change in midfoot pressure. The findings of this study were consistent with previous studies that showed that customized insoles caused a significant increase in pressure in the middle of the foot compared to semi-customized insoles (24-26). The alignment of the results was attributed to measuring the plantar pressure, which was done using a pressure measuring plate and with bare feet in both studies, even though a 3D printer was used to manufacture custom insoles.

Insoles are used to support the internal longitudinal arch of the foot and improve its condition. Customized insoles were more effective in enhancing the internal longitudinal arch structure. They increase the maximum pressure in the midfoot, which exerts more force. Over time, the maximum pressure in the plantar foot increased after six weeks, indicating the corrective force applied to the sole. Both customized and semi-customized insoles reduced the area surrounding the forefoot, but custom insoles were found to be more effective (22). This may be because custom insole manufacturing causes the reconstruction of the transverse arch, which results in less contact between the forefoot and the sole.

The study found no significant difference between customized and semi-customized insoles regarding pressure and contact surface in the hindfoot area. Previous research has shown that the heel area is exposed to the most pressure on the foot (27, 28). Custom insoles were found to result in less heel pressure, which may be due to the shape and height of the custom heel cup (22).

Limitations

Fourteen patients did not go to the center for the second test due to the spread and peak of the widespread and dangerous coronavirus disease 2019 (COVID-19) and the fear of infecting the child.

Recommendations

Choosing an advanced, uniform, and stable method for designing and making medical insoles for children with flat feet is essential. To achieve this, it is suggested that the current research be conducted with the help of scanners or other related design software. Additionally, further extensive research is needed to investigate the long-term effects of wearing insoles and changes in joint mechanics.

Conclusion

Although both custom-made insoles using CAD-CAM and semi-customized insoles were effective in biomechanical effects, such as plantar pressure of children with flat feet, custom-made insoles showed a more significant impact.

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Authors' Contribution

Study design and ideation: Alireza Taheri, Saeed Forghany
Scientific and executive support of the study: Pouyan Jafarian, Alireza Taheri, Saeed Forghany
Providing study samples: Pouyan Jafarian, Alireza Taheri, Saeed Forghany
Data collection: Pouyan Jafarian, Alireza Taheri, Saeed Forghany
Analysis and interpretation of the results: Alireza Taheri, Saeed Forghany
Specialized statistics services: Pouyan Jafarian, Alireza Taheri, Saeed Forghany
Manuscript Preparation: Pouyan Jafarian, Alireza Taheri, Saeed Forghany
Specialized scientific evaluation of manuscripts: Alireza Taheri, Saeed Forghany
Confirming the final manuscript to be submitted to the journal website: Pouyan Jafarian, Alireza Taheri, Saeed Forghany
Maintaining the integrity of the study process from the beginning to the publication, and responding to the referees' comments: Pouyan Jafarian, Alireza Taheri, Saeed Forghany

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Conflict of Interest

Authors have no conflict of interest. Dr. Alireza Taheri has been working as a faculty member in the School of Rehabilitation Sciences since 1997. Dr. Saeed Forghany has been working as a faculty member in this university since 2006. Mr. Pouyan Jafarian is a master's student in Orthosis and Prosthetics.

References

1. Webster J, Murphy D. Atlas of orthoses and assistive devices. Amsterdam, the Netherlands: Elsevier Health Sciences; 2019.
2. Ki SW, Leung AK, Li AN. Comparison of plantar pressure distribution patterns between foot orthoses provided by the CAD-CAM and foam impression methods. Prosthet Orthot Int 2008; 32(3): 356-62.
3. Menz HB. Foot orthoses: How much customisation is necessary? J Foot Ankle Res 2009; 2: 23.
4. Pauk J, Ezerskiy V, Raso JV, Rogalski M. Epidemiologic factors affecting plantar arch development in children with flat feet. J Am Podiatr Med Assoc 2012; 102(2): 114-21.
5. Harris EJ, Vanore JV, Thomas JL, Kravitz SR, Mendelson SA, Mendicino RW, et al. Diagnosis and treatment of pediatric flatfoot. J Foot Ankle Surg 2004; 43(6): 341-73.
6. Whitford D, Esterman A. A randomized controlled trial of two types of in-shoe orthoses in children with flexible excess pronation of the feet. Foot Ankle Int 2007; 28(6): 715-23.
7. Roth S, Roth A, Jotanovic Z, Madarevic T. Navicular index for differentiation of flatfoot from normal foot. Int Orthop 2013; 37(6): 1107-12.

8. Kothari A, Dixon PC, Stebbins J, Zavatsky AB, Theologis T. The relationship between quality of life and foot function in children with flexible flatfeet. Gait Posture 2015; 41(3): 786-90.
9. Evans AM. The flat-footed child -- to treat or not to treat: what is the clinician to do? J Am Podiatr Med Assoc 2008; 98(5): 386-93.
10. Evans AM, Rome K. A Cochrane review of the evidence for non-surgical interventions for flexible pediatric flat feet. Eur J Phys Rehabil Med 2011; 47(1): 69-89.
11. Halabchi F, Mazaheri R, Mirshahi M, Abbasian L. Pediatric flexible flatfoot; clinical aspects and algorithmic approach. Iran J Pediatr 2013; 23(3): 247-60.
12. Chen KC, Tung LC, Tung CH, Yeh CJ, Yang JF, Wang CH. An investigation of the factors affecting flatfoot in children with delayed motor development. Res Dev Disabil 2014; 35(3): 639-45.
13. Rome K, Ashford RL, Evans A. Non-surgical interventions for paediatric pes planus. Cochrane Database Syst Rev 2010; (7): CD006311.
14. Dunn JE, Link CL, Felson DT, Crincoli MG, Keysor JJ, McKinlay JB. Prevalence of foot and ankle conditions in a multiethnic community sample of older adults. Am J Epidemiol 2004; 159(5): 491-8.
15. Powell M, Seid M, Szer IS. Efficacy of custom foot orthotics in improving pain and functional status in children with juvenile idiopathic arthritis: A randomized trial. J Rheumatol 2005; 32(5): 943-50.
16. Gould N, Moreland M, Alvarez R, Trevino S, Fenwick J. Development of the child's arch. Foot Ankle 1989; 9(5): 241-5.
17. Khodaei B, Saeedi H, Jalali M, Farzadi M, Norouzi E. Comparison of plantar pressure distribution in CAD-CAM and prefabricated foot orthoses in patients with flexible flatfeet. Foot (Edinb) 2017; 33: 76-80.
18. Jahani MR, Jalalvand A. Effect of flat foot on excursions of lower limb joints during running. Shahid Sadoughi Univ Med Sci 2020; 28(2): 2373-83. [In Persian].
19. Ledoux WR, Hillstrom HJ. The distributed plantar vertical force of neutrally aligned and pes planus feet. Gait Posture 2002; 15(1): 1-9.
20. Rai DV, Aggarwal LM, Bahadur R. Plantar pressure changes in normal and pathological foot during bipedal standing. Indian J orthop 2006; 40(2): 119.
21. Razak AH, Zayegh A, Begg RK, Wahab Y. Foot plantar pressure measurement system: A review. Sensors (Basel) 2012; 12(7): 9884-912.
22. Redmond AC, Landorf KB, Keenan AM. Contoured, prefabricated foot orthoses demonstrate comparable mechanical properties to contoured, customised foot orthoses: a plantar pressure study. J Foot Ankle Res 2009; 2: 20.
23. Bus SA, Ulbrecht JS, Cavanagh PR. Pressure relief and load redistribution by custom-made insoles in diabetic patients with neuropathy and foot deformity. Clin Biomech (Bristol, Avon) 2004; 19(6): 629-38.
24. Xu R, Wang Z, Ren Z, Ma T, Jia Z, Fang S, et al. Comparative study of the effects of customized 3d printed insole and prefabricated insole on plantar pressure and comfort in patients with symptomatic flatfoot. Med Sci Monit 2019; 25: 3510-9.
25. Collins NJ, Hinman RS, Menz HB, Crossley KM. Immediate effects of foot orthoses on pain during functional tasks in people with patellofemoral osteoarthritis: A cross-over, proof-of-concept study. Knee 2017; 24(1): 76-81.
26. Chen Y, Li JX, Hong Y, Wang L. Plantar stress-related injuries in male basketball players: variations on plantar loads during different maximum-effort maneuvers. Biomed Res Int 2018; 2018: 4523849.
27. van der Wilk D, Dijkstra PU, Postema K, Verkerke GJ, Hijmans JM. Effects of ankle foot orthoses on body functions and activities in people with floppy paretic ankle muscles: a systematic review. Clin Biomech (Bristol, Avon) 2015; 30(10): 1009-25.
28. Umehara J, Ikezoe T, Nishishita S, Nakamura M, Umegaki H, Kobayashi T, et al. Effect of hip and knee position on tensor fasciae latae elongation during stretching: An ultrasonic shear wave elastography study. Clin Biomech (Bristol, Avon) 2015; 30(10): 1056-9.