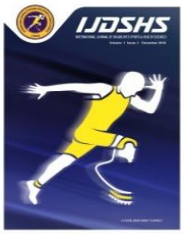

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RESEARCH ARTICLE

Effect of Custom Design Insole Applications with 3D Modelling on Baropodometric Parameters in Individuals with Pes Planus

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Abstract
It was aimed to investigate the effect of custom made insoles on baropodometric analysis parameters in individuals with pes planus, using objective measurement and production methods. 100 individuals with pes planus, aged between 4-18 years in the study. Individuals who met the inclusion criteria and the medial longitudinal arch index were included in the study. Valgus angles of individuals, plantar measurements of the feet before the use of insoles and after 6 months of the use of insoles were evaluated with the Sensor Medica® device. When the measurement results of the ankle valgus angles of the individuals before and after the insoles were examined, it was observed that there was a statistical decrease in the mean results in both feet ($p<0,05$). When the plantar pressure results were examined, the load on the medial side of the right foot was reduced significantly ($p=0,012$). Although there was a decrease in medial longitudinal arch of the right foot, it was not significant. There were no change in the lateral side of the right foot and the medial side of the right rearfoot. The load on the medial left rearfoot and the left medial longitudinal arch were reduced significantly ($p=0,004$, $p=0.021$). In study in individuals with pes planus, it was concluded that the foot should be well evaluated before and after technological based applications. Whether the insoles used provide benefits in foot development should be followed up with controls and their suitability should be checked, and changes in their physical capacities should be observed.

Keywords
Foot, 3D Design, Insole, Pes Planus, Plantar Pressure

INTRODUCTION

Pes planus is a foot deformity characterised by a decrease in arch height below normal values, decreased or absent height of the medial longitudinal arch, valgus of the rearfoot and abduction of the midfoot relative to the heel (Dare and Dodwell, 2014). According to studies, the incidence of pes planus has been reported to be 20-37% (Raj et al. 2022; Benvenuti et al.1995). Pes planus can be seen in two forms as flexible or rigid. In flexible pes planus, the cavity of the medial longitudinal arch is preserved when no load is applied on the foot, while flattening occurs in the cavity when load is applied. In rigid pes planus, the medial arch cavity is flat in both cases.

In a structurally normal foot in the neutral position, the load-bearing line passes through the 2nd metatarsal, the forefoot is perpendicular to the leg and the calcaneus is on the same line with the tibia. Collapses occurring in the medial longitudinal arch are due to increased pronation and decreased plantar flexion-adduction muscle force (Hajizadeh et al. 2022). Increased pressure in the medial line of 36 the foot also negatively affects physical performance. As the loads on the

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medial heel, 1st and 2nd metatarsals increase, all segments in the kinetic chain are affected and physical performance parameters such as jumping and changing direction decrease (Zhao et al. 2017).

In individuals with pes planus, the longitudinal arch of the foot may lose its ability to return to its initial height during weight bearing. Therefore, a foot orthosis should be able to regulate the arch height in different weight-bearing situations and prevent excessive pronation. Also, insoles used for individuals with pes planus should be flexible to facilitate adequate movement of the foot joints. In recent studies, flexible orthoses that maintain and/or increase arch height while standing have been emphasised (Williams and McClay, 2000; Banwell et al. 2014; Huang et al. 2004).

The prescription of insoles for pes planus aims to optimise the structure of the foot and the natural orientation of its associated function. This protects the medial longitudinal arch from abnormal stresses, preventing further deformity while attempting to promote optimal foot function and stability. Studies have shown that insoles reduce subtalar pronation and bring the results of lower extremity kinetic and kinematic analyses closer to normal (Murley et al. 2010; Mündermannet al. 2003). Materials and construction techniques in insoles are changing in parallel with the developing technology. Insoles made of Ethylene Vinyl Acetate (EVA) material using 3D modelling and CAD/CAM (Computer Aided Design / Computer Aided Manufacturing) method are widely used in the production of custom made insoles (Ahmad et al. 2012).

Plantar pressure analysis generates CAD data that is accurate to within a fraction of a millimetre. It also creates a 3D image of different areas of each foot in different colours to provide a clinical record of the analysis. There is software that measures plantar pressure on the basis of the scanned image. The information istransferred through mathematical transformation so that system users can determine the thickness required to design the insoles. The customised insoles (CAM), either hard or soft, are then manufactured using computer numerically controlled (CNC) milling machines. This method makes the design of the insoles much more precise, allowing rapid production and making them more ergonomic and comfortable (Huang et al. 2011; Turner et al. 2020). The aim of our study was to investigate the effect of 3D modelling of custom made insoles on baropodometric parameters in individuals with pes planus.

MATERIALS AND METHODS

Individuals

The study included 100 voluntary patients between the ages of 4-18 years who were diagnosed with Pes Planus. Sample size was calculated with 3.1.9.5 version of the G*power software. Type-1 error rate was accepted as 0.05 and power rate as 95%. The effect size was taken as 0.5 using the reference study data. The number of people included in the power analysis was 47. Individuals who had undergone foot and ankle surgery in the last 1 year, who had previously used insoles made with 3D modelling, who had pain, who had received treatment for pes planus, who were not ambulatory whose foot anatomical integrity was not complete were not included in the study.

The study was conducted in accordance with the Principles of the Declaration of Helsinki and was found ethically appropriate with the file number E-10840098-772.02-58338 at the meeting of Istanbul Medipol University Non-Interventional Clinical Research Ethics Committee dated 26/10/2020.

The individuals participating in the study were informed verbally and in writing about the purpose, duration, and evaluation parameters to be applied. "Informed Voluntary Consent Form" was read by the participants and their signatures and their consent was obtained. The study was conducted between October 2020 and March 2021 at the Aktif Prosthetics and Orthotics Centre and the Istanbul Medipol University Prosthetics and Orthotics Centre.

Method

In order to ensure that the measurement, evaluation and production methods used were in line with objective data, the arch height index was measured using a computer-aided baropodometry device from Sensor Medica and a Vulcan Computer Numerical Control (CNC) machine was used for insoles production. Evaluation and measurement analyzes of the foot were made by a physiotherapist. Insoles were applied by an orthotist. Insoles were started to be used for at least 5 hours a day, starting from 1-2 hours a day in the first week and gradually increasing the number of hours. It is expected to get used to in a period of approximately 2-3 weeks. The participant was called to the clinic and checked in to assess the improvement with the use of insoles, examine the pressure areas and adjust the corrections if necessary. Checks were made every 3rd, 6th and 12th months to assess whether the child still needs insoles. Insoles suitable for the length of the foot were provided to the participant when the foot length increased.

Age, gender, height, weight, body mass index and foot size were recorded as demographic information. Static and dynamic analyses were performed with a baropodometer for individuals with an arch height index below 0.275.

Medial longitudinal arch height index measurement system

The medial longitudinal arch height index measurement system was validated and recognised by Willams and Mc Clay in 2000. It is used to measure the height of the medial longitudinal arch (MLA) and categorises the foot into pes planus, normal and pes cavus. The ratio of the dorsal height measured at 50% of the foot length to the distance from the metatarsal head to the heel gives the MLA height index. If this ratio is 0.356 or greater, it is considered pes cavus, and if it is 0.275 or less, it is considered pes planus (Williams and McClay, 2000).

Pedobarographic analysis

Sensor Medica baropodometry device and Freestep software were used to measure plantar pressure distribution. There are many studies that use software with validity and reliability (Szczepanowska-Wołowiec et al.; Sgrò et al. 2014). Sensor Medica Freemed is a 120 x 50 cm foot plantar pressure distribution analysis device with a pressure platform made of aluminium, 8 mm thickness, 10000 sensors with a sensor life of 1,000,000 cycles, 2.5 dpi XY, 8 bit Z resolution, and a maximum pressure of 150 N/cm² (Sensor Medica, Rome, Italy). Pedobarographic evaluation was performed as static and dynamic analysis. During static analysis, the participants were in a static position with open eyes for 5 seconds. Dynamic analysis was performed by walking the individual on the platform for 6 rounds. In the static analysis, the ankle valgus angle was recorded. Ankle valgus angle measurements were measured with the goniometer in the Freestep software before and after insoles. In dynamic analysis, medial and lateral load distribution percentages (%), medial longitudinal arch distribution percentages (%), medial and lateral heel load distribution percentages (%), and load distribution percentages of the medial rearfoot (%) were measured for both feet in the sagittal axis in the middle of the stance phase of gait.

Custom made insoles production process with CAD/CAM method

Custom made insoles were produced in line with the recorded data and evaluations. As a result of the foot evaluation of the individuals participating in the study, it was deemed appropriate to use Ethylene Vinyl Acetate (EVA) material with a hardness value of Shore A 35 in all insoles. As a result of the pedobarographic evaluations of the individuals, medial and transverse arch reinforcements were added to the insoles according to the pressure distribution. In order to help palmar grip, supports were designed in 3D with EasyCad modelling interface. With the subtalar joint in neutral position, the medial longitudinal arch reinforcement was added to the insoles in a convex structure starting from the tuberosity of the calcaneus, reaching the apex at the navicular tubercle and extending to the head of the 1st metatarsal. After these procedures, the insoles from EVA material in blocks were adjusted in the CNC milling machine to be suitable for the patient's shoes and the compatibility was checked.

Data analysis

Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS inc. Chicago, IL, USA) was used for data analysis. Data expressed in numbers were expressed as n (%) and data expressed in measurements were expressed as arithmetic mean ± standard deviation (X±SD). Statistical significance level was accepted as $p<0.05$ in all analyses. Normality test showed that the data were not normally distributed. For this reason, the study was performed with Wilcoxon test, one of the non-parametric tests.

RESULTS

The study included 100 individuals with pes planus, 60 males and 40 females aged 4-18 years. The mean age of the individuals was 10.32±3.19 years, mean height was 139.18±19.65 cm, mean body weight was 39.12±16.65 kg, mean Body Mass Index (BMI) was 19.25±3.95 kg/m^2 and mean foot size was 35.07±4.45.

When the valgus angle measurement results of the individuals (Table 1) and the comparison of valgus angles according to age range (Table 2) were analysed before and after the insoles, it was seen that there was an average 32% decrease in the left and right foot. The most statistically strongest results were the reduction in valgus angle (p<0.05).

The results of baropodometric measurements before and after 6 months of insoles use are shown in Table 3 and the comparison of plantar pressure measurements according to the age range of the individuals is shown in Table 4. According to the results of baropodometric measurements before and after 6 months of insoles, the load on the medial aspect of the right foot decreased significantly (p=0.012), although the load distribution in the medial longitudinal arch of the right foot decreased on average, it was not statistically significant (p>0.05). The load on the left medial rearfoot and medial longitudinal arch of the left foot decreased significantly (p=0.004, p=0.021). Although the mean load distribution on the medial left foot decreased, it was not statistically significant (p>0.05).

Table 1. Comparison of valgus angles of individual

	Variables	Min- Max Before Insoles	Min- Max After Insoles	Before Insoles X±SD	After Insoles X±SD	Wilcoxon Signed Ranks Test	
						z	p*
STATIC ANALYSIS	Left foot valgus angle (º)	5.00-21.00	2.00-16.00	11.06±3.29	7.76±2.87	-8.081	**0.005***
	Right foot valgus angle (º)	4.00-18.00	1.00-16.00	10.8±3.16	7.04±2.94	-8.527	**0.005***

%: Percentage, SD: Standard Deviation, X: Mean, Wilcoxon Signed Ranks Test, Statistical significance p<0,05*

Table 2. Comparison of valgus angles according to age range of individual%: Percentage, SD: Standard Deviation,

	Variables	Before Insoles X±SD	After Insoles X±SD	Wilcoxon Signed Ranks Test	
STATIC ANALYSIS	**4-10 age range (N=55)**			z	p*
	Left foot valgus angle (º)	10.65±3.2	7.67±2.63	-5.940	**0.005***
	Right foot valgus angle (º)	10.58±3.23	6.87±2.92	-6.266	**0.005***
	11-18 age range (N=45)				
	Left foot valgus angle (º)	11.55±3.36	7.85±3.18	-5.515	**0.005***
	Right foot valgus angle (º)	11.06±3.08	7.25±3.99	-5.792	**0.005***

X: Mean, Wilcoxon Signed Ranks Test, Statisticalsignificance p<0.05*

Table 3. Comparison of plantar pressure measurements of individuals

	Variables	Before Insoles X±SD	After Insoles X±SD	Wilcoxon Signed Ranks Test	
				z	p*
DYNAMIC ANALYSIS	Left Foot Lateral (%)	22.96±4.32	23.73±3.94	-1.710	0.074
	Left Foot Medial (%)	26.61±4.07	27±4.11	-0.799	0.424
	Right Foot Lateral (%)	25.36±4.84	24.43±4.45	-1.319	0.187
	Right Foot Medial (%)	23.46±3.92	22.28±4.29	-2.332	**0.012***
	Medial Arch of the Left Foot (%)	5.09 ±5.54	3.87±4.74	-2.309	**0.021***
	Medial Arch of the Right Foot (%)	4.31 ±4.46	4.01±4.68	-0.684	0.494
	Left Medial Rearfoot (%)	16.94±5.05	15.91±5.58	-2.878	**0.004***
	Right Medial Rearfoot (%)	17.41±5.04	16.74±5.37	-1.518	0.129

%: Percentage, SD: Standard Deviation, X: Mean, Wilcoxon Signed Ranks Test, Statistical significance p<0.05*

Table 4. Comparison of plantar pressure measurements according to age range of individuals

Variables	Before Insoles X±SD	After Insoles X±SD	Wilcoxon Signed Ranks Test	
			z	p*
4-10 age range (N=55)				
Left Foot Lateral (%)	22.72±4.46	23.25±3.72	-1.142	0.253
Left Foot Medial (%)	26.29±3.90	26.47±3.98	-.389	0.697
Right Foot Lateral (%)	25.58±5.21	24.74±4.95	-.920	0.358
Right Foot Medial (%)	23.23±3.98	22.28±4.73	-1.525	0.127
Medial Arch of the Left Foot (%)	5.26 ±4.85	3.48±4.51	-2.671	**0.008***
Medial Arch of the Right Foot (%)	4.56 ±3.88	3.29±3.57	-1.788	0.074
Left Medial Rearfoot (%)	15.87±6.22	16.08±3.92	-1.466	0.143
Right Medial Rearfoot (%)	17.09±5.10	16.35±4.58	-.666	0.505
11-18 age range (N=45)				
Left Foot Lateral (%)	23.17±4.15	24.12±4.18	-1.278	0.201
Left Foot Medial (%)	27±4.36	27.61±4.18	-.822	0.411
Right Foot Lateral (%)	24.95±4.35	24.06±3.69	-.972	0.331
Right Foot Medial (%)	23.70±3.82	22.46±3.76	-1.858	0.063
Medial Arch of the Left Foot (%)	5.26 ±6.59	5.06±6.05	-.054	0.957
Medial Arch of the Right Foot (%)	4.34 ±5.31	5.88±7.26	-1.568	0.117
Left Medial Rearfoot (%)	15.73±4.94	17.76±6.03	-2.762	**0.006**
Right Medial Rearfoot (%)	16.41±5.62	18.80±5.37	-2.963	**0.003***

%: Percentage, SD: Standard Deviation, X: Mean, Wilcoxon Signed Ranks Test, Statistical significance p<0.05*

DISCUSSION

In our study, the effect of custom made insoles produced by CAD/CAM method on baropodometric parameters in individuals with pes planus was investigated. Individuals with pes planus were included in our study by calculating the arch height index. In 200 feet, the rearfoot eversion angle was between 4 degrees and 21 degrees. After 6 months of insoles use, 32% reduction in ankle valgus angle was observed. Decreased valgus angle in both feet, decreased contact surface of the medial longitudinal arch, decreased load on the medial side of the foot and increased load on the lateral side during walking showed that the biomechanical alignment approached normative values. In our study, it was concluded that as age increases, the physiological pes planus-based foot medial loading decreases due to normal development.

The medial longitudinal arch develops in the first decade of life. In many scans, although the majority of children are born with pes planus, the prevalence of pes planus has been reported to be between 44% and 68% at the age of 3 years and between 14% and 25% at school age (Sheikh and Feldman, 2015; Drefus et al. 2017). Bresnahan and Juanto suggested that paediatric flatfoot should not be ignored and conservative corrective treatment procedures are appropriate before surgical interventions (Bresnahan and Juanto, 2015). Hsieh et al. (Hsieh et al. 2018). evaluated 52 children aged 3-10 years with flexible pes planus in a prospective randomised controlled clinical trial in which 26 children used insoles made of EVA for 12 weeks, while 26 children in the control group did not use insoles. They found that 76.2% of the children improved and the treatment group showed significant improvements in pain/discomfort, physical health and function, stair climbing time, transfer and basic mobility compared to the control group. In this study, which was followed up for 12 weeks and subjective scales were used as measurement methods, the effects of age range and custom made insoles were seen to reduce the loading, which supported our study. The contact of the medial longitudinal arch support of the insoles with the foot is thought to reduce the load on the arch structures by preventing increased pronation of the foot, and this result is supportive of the literature. As reported in the literature, if appropriate and effective treatment is performed in the early period, it reduces the presence of deformity. Xu R. et al. (Xu R. et al. 2019) compared the effects of CAD/CAM produced insoles and prefabricated insoles on plantar pressure and comfort before insoles and after 8 weeks of insoles use. 80 individuals with symptomatic pes planus in the control group used prefabricated insoles and those in the experimental group used customised insoles. They found that there was an increase in the comfort of the patients in the experimental group, a significant decrease in the load on the metatarsal heads, and an increase in midfoot pressure in the control group. It is seen that customized 3D printed insoles were more effective than prefabricated insoles and offered better comfort for patients with symptomatic flatfoot.

Although there are studies using angles that can be measured by methods in which radiography is accepted as the gold standard when examining the foot structure or comparing these methods with pedobarographic methods, evaluations related to foot structure are most commonly performed with pedobarographic measurements in the literature (Sheikh and Feldman, 2015). Measurement and evaluation methods are updated with the advancement of technology. In this study, EasyCad modelling interface, which is an alternative way for design and production of insoles and orthoses with much faster, reliable, custom made designs and reinforcement needs, was revealed by using 3D design technology (Daryabor et al.2022). Lee et al. (Lee et al. 2022). examined the effect of 3D designed insoles in paediatric flexible pes planus patients. They evaluated the individuals with radiographic images and FootScan pedobarography device. They concluded that the use of custom made insoles with 3D modelling had a corrective effect on valgus angle, but did not affect the change in midfoot pressure in dynamic plantar pressure analysis. Similarly, in our study, it was observed that valgus angles decreased after the use of insoles in both age groups. In our study, in which radiographic method was not used, evaluation was performed with Sensor Medica device similar to FootScan device. The most important advantage of pedobarographic measurement compared to radiographic measurements is that it can evaluate the foot not only statically but also dynamically during the gait cycle (Yin et al. 2018). Pedobarographic devices are an important evaluation tool in terms of orthosis selection and application.

Sheykhi-Dolagh et al. (Sheykhi-Dolagh et al. 2015) compared the effect of polypropylene material (UCBL), semi-rigid and soft insoles on foot mobility and arch height index in a study of 20 individuals with flexible pes planus. UCBL insoles gave the best results in AHI with its rigid structure and prevented the mobility of the arches of the feet. However, they reported that UCBL insoles were stiff and painful during walking. In our study, Shore 35-40 insoles made of medium hard EVA were used. Thus, it was concluded that the insoles should be made by considering the mobility of the foot structure in different movement situations, taking into account the materials and methods. It was thought that AHI score could be preferred as an objective measurement in the clinic due to its ease of use, and objectivity could be increased with pedobarography device.

Alsancak et al. (Alsancak et al. 2021) associated age, sex and body weight with the diagnosis of pes planus according to the footprints obtained by pedobarography method in 335 children aged 6-10 years. They concluded that the prevalence of pes planus decreased with increasing age. In a cross-sectional study, the prevalence of pathological pes planus was 10.3% in a total of 667 children aged 7-14 years, but it was reported that this prevalence decreased with age (Sadeghi-Demneh et al. 2018). In another study, when dynamic footprints of both feet of a total of 1059 children aged 6-13 years were taken, it was concluded that the prevalence of pes planus decreased with age and the rigid arch structure of the foot was formed at the age of 12-13 years (Khodaei et al. 2017). In a 3-year prospective study, Martínez-Nova et al. reported that paediatric pes planus and pronated foot transformed into a neutral Foot Posture Index-6 (FPI-6) foot type with increasing age. It has been reported that pronated foot posture can be expected in children under 9-10 years of age and may decrease spontaneously without any treatment (Martínez-Nova et al. 2018). In time, foot bone alignment and structure deteriorate and the contact area in the midfoot increases. In our study, it was observed that individuals with pes planus contacted the medial heel more due to valgus in their feet, and the percentage of forefoot contact decreased as a result of supination occurring in the forefoot relative to the rearfoot. At the same time, this situation decreases with age. 6-month regular use of insoles was found to be effective in correcting sole pressure distributions and preventing overload in certain areas by increasing the contact surface. Pedobarographic evaluation should be performed by the orthotist and changes in foot pressure distribution with age should be observed. If there is a risk, we think that the patient should be followed up and orthotics should be started at an early age.

Jarboe et al. (Jarboe et al. 2003) stated that the use of insoles should create a wider contact area to ensure the comfort of the sole of the foot. Based on this statement, the evaluations performed before and after the use of insoles in our study showed that the insoles could distribute the loads on the foot more accurately by contacting the ground and the sole of the foot in a wider area. We think that the production method of the insoles is an important factor in the approximation of the foot to the neutral position with customised insoles.

Studies show that the use of baropodometric parameters in the pre- and post-assessment of foot-ankle applications in prosthetic orthotic centres contributes to accurate decision-making not only for the production of insoles but also for the production of other planned orthoses. Our study shows that custom made insoles produced with computer-aided design positively affect the static and dynamic plantar load distribution of individuals. In our study, in which we included individuals with pes planus in the 4-18 age group, it was concluded that the foot should be evaluated well before and after technological-based applications. Although insoles produced by CNC machine with 3D modelling method have become widespread in recent years, studies in this field are very limited in terms of both the number of individuals and the follow-up period. The production of customised insoles in a short time reduces the practitioner error. The follow-up of CAD/CAM insoles application for 6 months is the strength of our study. It was concluded that randomised controlled long-term studies with the addition of a control group are needed.

Conclusion

In our study, it was concluded that insoles made with CAD/CAM production, which bring the subtalar joint to a neutral position and allow natural movement at the same time, are effective in balancing load distribution and reducing medial loading in individuals with pes planus. We think that the evaluation of foot-ankle structures by specialists preschool and during school age would be beneficial in terms of biomechanics.

Conflict of Interest

No conflict of interest is declared by the authors. In addition, no financial support was received.

Ethics Statement

The study was conducted in accordance with the Principles of the Declaration of Helsinki and was found ethically appropriate with the file number E-10840098-772.02-58338 at the meeting of Istanbul Medipol University Non-Interventional Clinical Research Ethics Committee dated 26/10/2020.

Author Contributions

D.T., E.A.: Study design, development of the study, review of data analysis Ö.A.: Research, data collection, data analysis, NHY Article writing, data analysis, translation

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