RESEARCH ARTICLE

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The Effect of Customized 3D Printed Insoles on Physical Activity Level, Balance, and Physical Performance in Patients with Pes Planus: A Randomized, Placebo Controlled, Double-Blinded Study

ABSTRACT

Objective: This study aimed to investigate the effects of individually designed insoles on physical activity level, balance, and functional performance in patients with pes planus.

Materials and Methods: 38 participants were divided into 2 groups as 3D printed (n=20) and placebo (n=18). In the 3D printed group, medial longitudinal arch support, medial wedge of the foot, medial heel wedge, and transverse arch support were given to the insoles according to the needs of the participants. The placebo group received placebo insoles. Muscle strength, range of motion, static and dynamic balance, physical and physical activity levels were measured at baseline, and eight weeks later (clinicaltrials.gov ID: NCT05306886).

Results: Muscle strengths of the plantar flexion (p=0.030) and eversion increased after the use of insoles in the 3D printed and placebo groups (p=0.020). There was no change in static balance in both groups (p=0.386), but there were significant improvements in dynamic balance in 3D printed groups (p=0.019). Gait speed improved in both 3D printed (p=0.001) and placebo groups (p=0.015). There was no significant difference in the explosive power between the groups (p=0.272). The shuttle run test improved significantly in the placebo group (p=0.015), but no significant change was observed in the 3D printed group (p=0.886). While the physical activity levels in the placebo group showed a significant improvement (p=0.017), the physical activity level decreased in the 3D printed group (p=0.489).

Conclusions: In this study, it was found that the use of personalized insoles is effective in improving physical activity, balance, and performance, while placebo insoles were found to be more effective in increasing muscle strength and explosive muscle strength.

Keywords: Balance, Physical Functional Performance, Pes Planus.

Pes Planuslu Hastalarda Kişiye Özel Tasarlamış 3D Baskılı Tabanlıkların Fiziksel Aktivite Düzeyi, Denge ve Fiziksel Performans Üzerine Etkisi: Randomize, Plasebo Kontrollü, Çift-Kör Bir Çalışma

ÖZET

Amaç: Bu çalışmanın amacı, pes planuslu hastalarda fiziksel aktivite seviyesi, denge ve fonksiyonel performans üzerine kişiye özel olarak tasarlanmış tabanlıkların etkilerini incelemektir.

Gereç ve Yöntem: 38 katılımcı 3D baskılı (n=20) ve plasebo (n=18) olmak üzere 2 gruba ayrıldı. 3D baskılı grupta, katılımcıların ihtiyacına göre tabanlıklara medial longitudinal ark desteği, ayak medial kaması, topuk medial kaması ve enine ark desteği verildi. Plasebo grubu ise plasebo tabanlık aldı. Kas gücü, hareket açıklığı, statik ve dinamik denge, fiziksel ve fiziksel aktivite seviyeleri başlangıçta ve sekiz hafta sonra ölçüldü (clinicaltrials. gov ID: NCT05306886).

Bulgular: Plantar fleksiyon ve eversiyon kas kuvvetleri, 3D baskı ve plasebo gruplarında artış gösterdi (sırasıyla p=0.030 ve p=0.020). Her iki grupta da statik denge değişmedi (p=0.386), ancak 3D baskı gruplarında dinamik denge önemli ölçüde arttı (p=0.019). Yürüme hızı hem 3D baskı (p=0.001) hem de plasebo gruplarında (p=0.015) arttı. Gruplar arasında patlayıcı güçte anlamlı farklılık görülmedi (p=0.272). Shuttle Run testi, plasebo grubunda anlamlı olarak gelişti (p=0.015), ancak 3D baskı grubunda anlamlı değişim gözlemlenmedi (p=0.886). Plasebo grubunda fiziksel aktivite seviyelerinde önemli bir gelişme görülürken (p=0.017), 3D baskı grubunda fiziksel aktivite seviyesi azaldı (p=0.489).

Sonuç: Bu çalışmada, kişiselleştirilmiş tabanlıkların kullanımının fiziksel aktivite, denge ve performansı iyileştirmede etkili olduğu, plasebo tabanlıkların ise kas gücü ve patlayıcı kas gücünü artırdığı bulunmuştur.

Anahtar Kelimeler: Denge, Fiziksel Performans Seviyesi, Pes Planus.

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INTRODUCTION

The foot is an important organ in the human body and acts as a shock absorber for the ground reaction forces exerted on the body (1). It accomplishes this task through the healthy coordination of its joints, ligaments, and muscles. However, disruptions in this healthy coordination can lead to deformities (2). One such deformity, pes planus, is characterized by a low medial longitudinal arch, often accompanied by pronation of the subtalar joint (3). Predisposing factors for pes planus may include degeneration of the plantar fascia, decreased flexibility of the spring ligament, and dysfunction of the tibialis posterior tendon (4, 5).

Pes planus is a foot deformity and can cause pain, instability, and increased risk of injury. Treatment options for patients with this condition include conservative methods such as plaster applications, activity modification, weight loss, shoe modification, taping, foot-ankle orthoses, and custom-made insoles (6, 7). In patients with pes planus deformity, the load on the medial part of the foot increases, and this leads to excessive valgus deformity in the hindfoot (8). The midfoot slides in the transverse tarsal joint with the emergence of the talus head (9). The traction angle of the Achilles tendon shifts laterally to the subtalar joint, promoting eversion. Additionally, Achilles contracture may exacerbate these deformities, potentially resulting in equinus deformity (10).

It is thought that the insoles used in the treatment of pes planus may provide healthy foot mechanics by supporting the foot, allowing painless performance of daily activities and sportive activities, and may also help to reduce the risk of injury (11). Therefore, various types of insoles are used in the treatment of pes planus as a part of conservative treatment (12). However, it is not known which type of insoles is the most effective (13). Recent studies have shown that customized 3D insoles can positively affect gait function and biomechanics (7, 14). However, the number of blinded studies with placebo insoles is limited and more research is needed on the efficacy of custom-made insoles in the treatment of pes planus.

Although the impact of insole usage in individuals with pes planus has been frequently examined in the literature, studies investigating the effectiveness of personalized insoles in treating this condition are relatively scarce. Similarly, there is a limited number of studies in the literature wherein participants were blinded with placebo insoles lacking any support. This study aimed to examine the effects of 3D printed insoles tailored to each patient on physical activity levels, balance, and functional performance in individuals with pes planus.

MATERIAL AND METHODS

A prospective, randomized, controlled, double-blinded design was carried out in this study. Forty-five patients who signed the written informed consent and fulfilled the inclusion criteria were included in the study. Participants aged 18-45 years with pes planus who applied to the Fizyotermal Inc. clinic were included in this study. Permission was obtained from Bolu Abant Izzet Baysal University Clinical Research Ethics Committee (2021245-369) for this study. This study was registered to the NIH Clinical Trials registry, clinicaltrials.gov ID: NCT05306886.

Inclusion criteria were; having a minimum subtalar pronation angle of 5 degrees during standing posture, having a minimum score of + 6 on the Foot Posture Index (FPI) scale, not having received any treatment from the foot area in the last 6 months, having bilateral pes planus. Exclusion criteria were; a history of lower extremity surgery, being an active athlete, pregnancy or diagnosis of malignancy, having a dysfunction such as severe neurological involvement, immobility, cooperation problems that restrict physical activity, having more than 1 centimeter (cm) of lower limb inequality, having a different orthopedic disease that may affect lower limb biomechanics, receiving a different treatment for pes planus at the same with study.

Demographic information, foot posture index, subtalar angles, and leg length were collected in the initial evaluations of the participants. After these data were obtained, dynamic gait analyses and static analyses were taken in a pedobarographic gait analysis device. The footwear habits of each participant were questioned to determine the type of shoes in which the insoles would be used. The patients were divided into two groups by simple computer-assisted randomization as 3D printed and placebo insole groups. Participants were randomly divided into 2 groups without being told which group they were allocated and outcome measurements performed by a physiotherapist who was not aware of group allocation.

Sample size calculation was made with G*Power (Universität Düsseldorf, Kiel, Germany). The sample size was calculated for foot posture index according to Buldt et.al’s study (d=0.83) and to achieve $\alpha<0.05$ and $1-\beta=80\%$, 19 patients were required for each group (15).

Outcome Assessments: After collecting demographic information, the participants were called again and normal joint movements, muscle strength, balance evaluations, functional performance tests, and IPAQ questionnaire were performed to determine the level of physical activity. Muscle strength, balance assessments, and functional performance tests were conducted at baseline and eight weeks after the initial assessment.

Foot Posture Index: This test was administered to the participants once during their first visit to evaluate their foot posture. Participants with a test result of +6 points and above were included in the study (16, 17).

Subtalar Angle: Subtalar angle, the range of motion (ROM) of the subtalar joint can be measured with a goniometer to determine whether the hindfoot is in rotation. The severity of subtalar pronation was determined by the goniometric measurement of the subtalar joint (18).

Range of Joint Motion: Ankle inversion/eversion angles were measured with a goniometer to measure the ankle range of motion of the participants. The results were measured three times and mean scores were recorded in degrees.

Muscle Strength Measurement: Muscle strength tests were performed on foot dorsiflexion + inversion, and foot eversion movements to see whether there was a change in muscle strength with insoles. A hand dynamometer was used for the measurements (JTech Commander Power Track II Manual Muscle Testing Dynamometer, USA). Measurements were performed three times for each movement and the highest value was recorded in pounds.

Flamingo Balance Test (FBT): To measure the static balance of the participants, the Flamingo balance test was performed with eyes closed/eyes open. Each participant was asked to place the ankle of the non-tested side behind the knee of the leg on the tested side and stand on one leg for 1 minute. During this time, the number of body oscillations was recorded. Since there were participants who could not complete the one minute, the time spent standing on one leg during the test was also measured and recorded with a stopwatch.

Y-Balance Test (YBT): The previously proven Y-Balance Test Lower Quart (YBT-LQ) was used to measure the dynamic balance of the participants. Participants were asked to stand on one foot on a platform at the center point where all directions intersected while pushing a wooden block on each bar with the other foot. Three measurements were taken in each direction. Three measurements were taken in each direction. The farthest distance was recorded in centimeters. Composite score was calculated as reach distance (cm)/leg length of stance leg (cm) x 100.

Standing Long Jump Test(SLJ): To evaluate the explosive power of the participants, the standing long jump test, the reliability of which has been previously proven and correlated with the vertical jump test, was used (19). During this test, the participants were asked to jump the longest distance they could jump with both feet from the starting line without their feet touching. Each participant performed 3 repetitions. Measurements were made with the help of a tape measure. The highest value was recorded in centimeters.

10-Meter Walk Test (10MWT): To see how the insoles affected the short-term walking speed of the participants, a 10-meter walking test was performed. Participants were asked to walk a previously marked distance of 10 meters at their normal walking speed. The results were measured with a stopwatch and recorded in seconds.

Shuttle Running Test (SRT): A shuttle running test was applied to evaluate the agility of the participants. 2 lines were drawn 7 meters apart. The participant was asked to run as fast as possible behind the start line with the start command. When the participant reached the finish line, he/she turned back to the start line and the time he/she reached the start line for the second time was measured with a stopwatch and recorded in seconds.

Heel Raise Test (HRT): The heel raise test was used to test the ability of the tibialis posterior muscle to maintain inversion in the hindfoot while the forefoot was stabilized on the ground. In this test, which has proven to be reliable, the participants were asked to lift their heels off the floor by rising on tiptoe until fatigue while the forefoot was in inversion on one leg and with the knee in extension. The cadence of the heel-raise cycle was regulated to 60 per minute using a metronome. Participants were directed to raise the heel as high as possible during each heel rise until they could no longer perform additional repetitions while maintaining straightness in the knee and trunk. The number of repetitions was recorded (20).

International Physical Activity Questionnaire (IPAQ): The IPAQ Short Form was used to measure the physical activity levels of the participants and to measure whether they changed with insoles. In this 7-question questionnaire, the Turkish validity and reliability study of which was conducted by Öztürk (2005), the different levels of physical activity levels of individuals in the last week were calculated and recorded in METs (21).

Foot Analysis and Insole Application: All participants walked on a pedobarographic gait analyzer (Postural Electronic Baropodometric Multi-Sensor, Italy), and foot pressure measurements were taken. Among the 3 successful steps, the right and left steps most appropriate for normal gait were selected and recorded. On the same platform, static analyses were taken by asking the participants to stand still while looking straight ahead. Within the scope of the data obtained from the gait analyzer, insoles were drawn with the Milletrix Applicazione MFC program in a computer environment as medial longitudinal arch support, forefoot medial wedge, medial heel wedge, and transverse arch support if necessary. All drawings were made by the researcher's physiotherapist. While drawing the insoles of the intervention group, the MLA height was determined according to the navicular height of each participant while standing. The forefoot medial wedge, medial heel wedge, and transverse arch reinforcement given for each insole were determined according to each participant's analysis. Forefoot medial wedge 3-6 mm, medial heel wedge 1-3 mm, and transverse arch reinforcement 6-8 mm were given and modeled. The total average height of the insoles in the 3D printed group was calculated as 18.9 mm. The placebo group was modeled with only 2 mm MLA support in the same drawing program. The total height of the insoles in the placebo group was 8.5 mm. Since there is no prescription determined in the literature on the insole design process, all insole design processes and production stages were carried out by the researcher physiotherapist to prevent differences that may arise from the evaluators in this study. The production of the insoles, the design of the insoles through computer software, and the production of the resulting model with a 3D printer eliminated the changes belonging to the practitioner and ensured that the application was made with more precise measurements (24). After the design process was completed, the insoles were transferred to the model processing machine Computer Numerical Control (CNC) machine (CNC router, Italy), and the insoles were produced. To prevent the effects caused by the hardness of the insoles, ethyl vinyl acetate (EVA) of medium hardness (shore 50), whose effectiveness has been previously proven, was used. Standardization was ensured between the insoles through the design process, the production phase, and the materials used, and it was aimed to exclude the differences that would arise at these stages. The produced insoles were corrected with a milling machine to adapt to the participant's shoes. For the upper coating of the finished insoles, 1mm thick fabric was used (Figure 1).

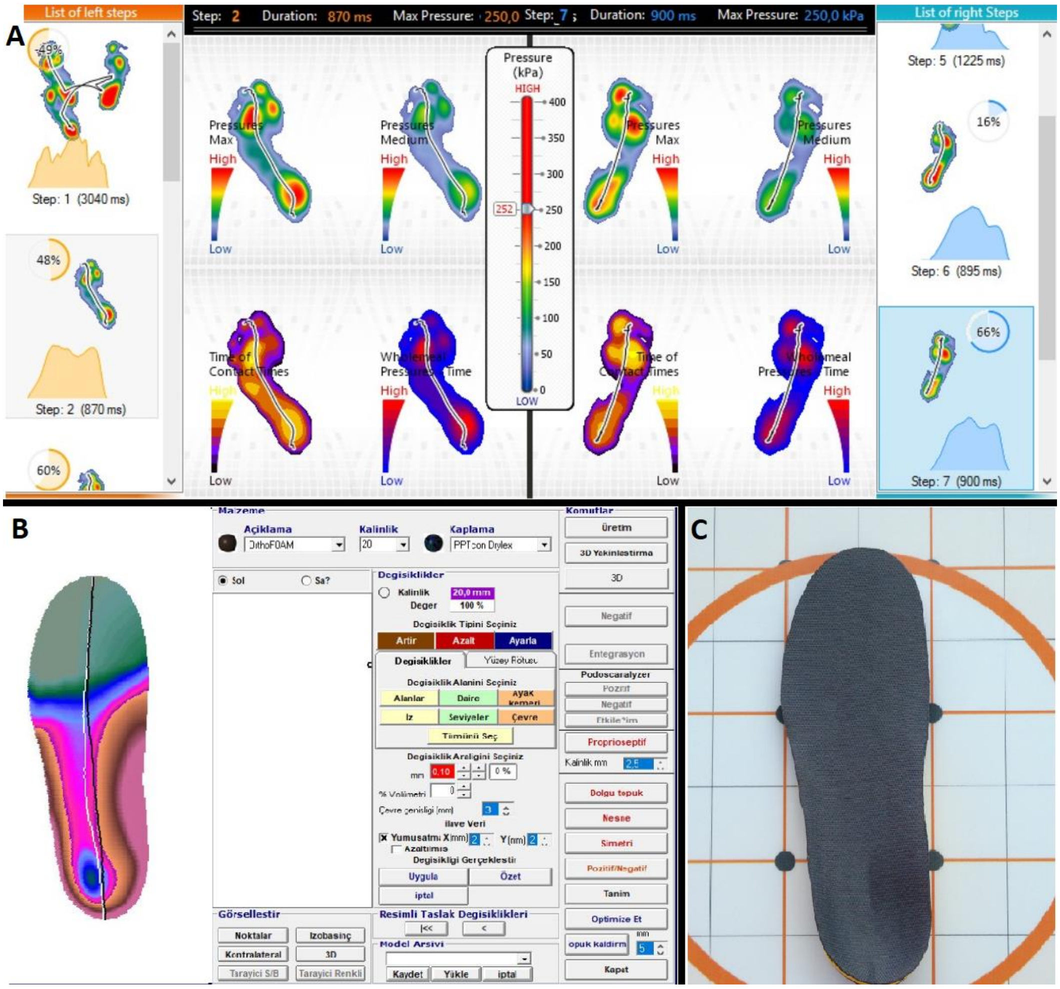

Figure 1. Foot analysis and 3D printed insole**.** A: Pedobarographic analysis, B: Computerized insoles design according to the analysis results, C: Personilized 3D printed insole

Statistical Analysis: Mean and standard deviation were used for descriptive statistics. Shapiro-Wilk test was applied for normal distribution of the obtained data. All evaluation results obtained were analyzed using appropriate statistical methods. Paired-Samples t-Test was applied for comparisons within both 3D printed and placebo groups. An Independent-Sample t Test was applied for comparison between groups. The chi-square test was applied for gender distributions. The statistical significance threshold for all tests was set at $p < 0.05$. Statistical analysis of the data was carried out using SPSS 22.0 for Windows.

RESULTS

A total of 45 participants were included between December 2021 and July 2022, 38 of whom completed this study (Figure 2). Participants' gender, age, body mass index, foot posture index, and subtalar angles were evaluated (Table 1). In the 3D print group, there were 10 (50%) males and 10 (50%) females, while in the placebo group, 13 (72.2%) were males and 5 (27.8%) were females. There was no significant difference between the sex distribution of the groups (p=0.585). Additionally, there were no significant differences between the age, body mass index, and subtalar angle of the participants at baseline (respectively p=0.839, p=0.556, p=0.109). However, there was a significant difference between the groups in foot posture index scores (p<0.05). The normal distribution of the data of the groups among all outcome assessments was analyzed using the Shapiro-Wilk test, and it was found that all parameters showed a normal distribution (p>0.05).

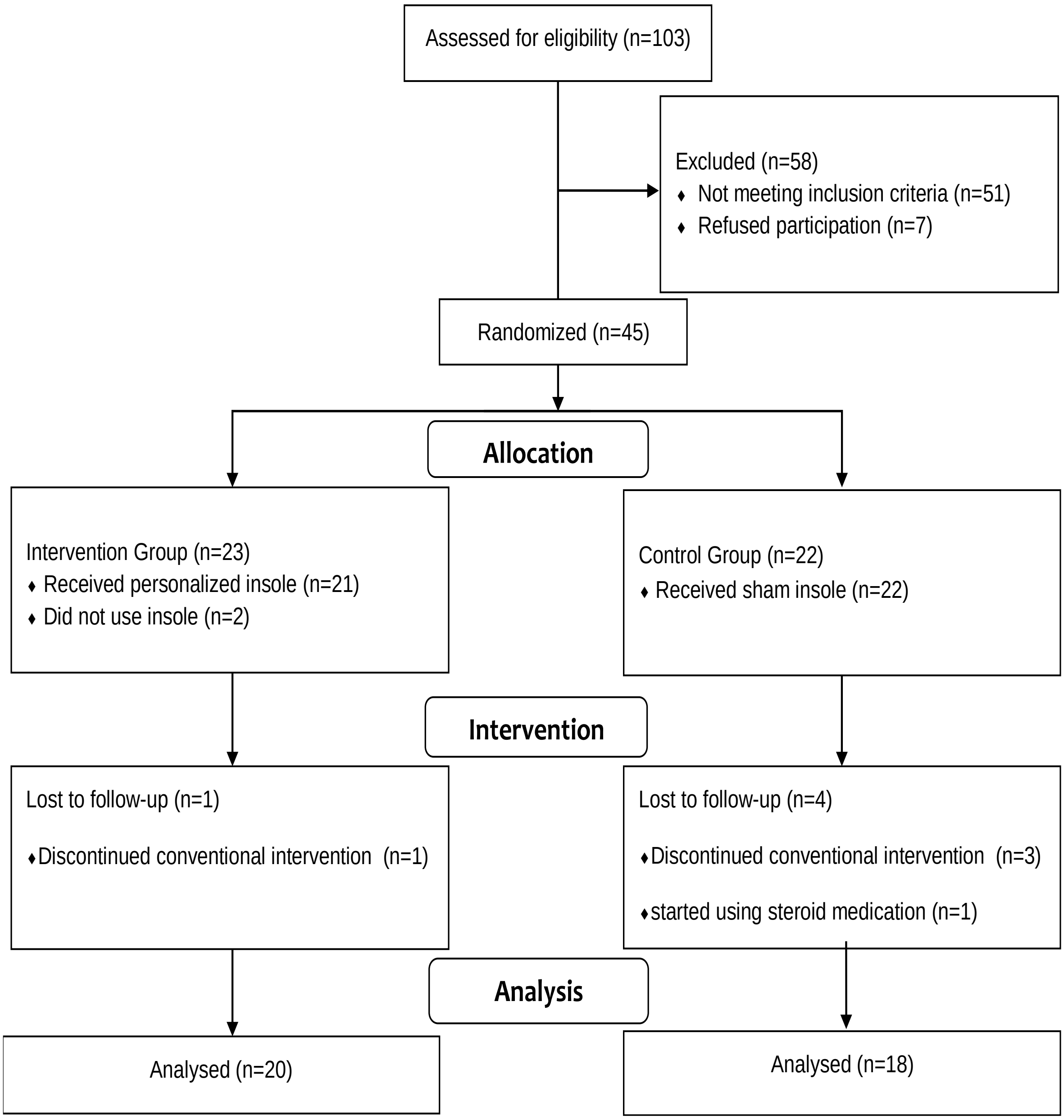

Figure 2. Flowchart

Table 1. The descriptive and statistical results of age and symptom onset of participants

	3D printed Group (n=20)	**Placebo Group (n=18)**		
	X±SD	**X±SD**	**t**	**P***
Age (year)	24.01±4.24	23.66±5.74	0.205	0.839
BMI(Kg/cm^2)	23.55±4.68	22.76±3.31	0.595	0.556
Foot posture index	10.35±1.30	9.11±1.49	2.709	**0.010**
Subtalar angle	10.4±1.95	9.22±2.47	-1.643	0.109

BMI: Body mass index, *: independent samples t test, p<0.05

In this study, the FPI score values of the groups were calculated using Cohen's d formula, revealing an effect size of 0.88, with the study's power determined to be 86% through post-hoc power analysis.

Significant differences were observed in the 3D-printed group in plantar flexion and dorsiflexion muscle strength, as well as in the YBT and the 10 MWT, with corresponding p-values of 0.024, 0.030, 0.019, and 0.001, respectively. While the placebo group exhibited significant changes in ROM and SRT, HRT, and IPAQ scores, with respective p-values of 0.026, 0.015, 0.012, and 0.017. Furthermore, both groups demonstrated significant differences in eversion muscle strength between pre- and post-test results (p=0.020, p=0.028). No significant differences were found in the remaining outcome measures (p>0.05) (Table 2).

Table 2. Results of the pre- and post-tests comparison for both groups

	3D printed Group (n=20)			**Placebo Group (n=18)**		
	Pre-test	Post-test	**p**	Pre-test	Post-test	**p**
Eversion ROM	29.05±6.58	28.62±4.76	0.706	29.55±4.44	31.91±3.82	**0.026**
Inversion ROM	37.01±5.61	37.25±10.8	0.855	41.55±10.32	40.72±8.7	0.818
Muscle strength DF (lbs.)	28.5±4.17	30.47±4.84	**0.024**	29.77±4.75	31.61±5.08	0.116
Muscle strength PF (lbs.)	28.6±4.38	31.02±3.10	**0.030**	30.44±3.75	31.36±3.29	0.273
Muscle strength EV (lbs.)	24.95±5.93	27.55±4.26	**0.020**	25.47±3.38	28.41±5.09	**0.028**
Flamingo balance test	12.13±2.42	13.61±1.81	0.386	11.87±1.74	12.40±1.62	0.479
Y balance test total (cm)	217.80±6.15	240.38±4.62	**0.019**	239.47±5.82	241.11±5.97	0.241
Standing long jump (cm)	130.9±31.12	126.8±33.79	0.145	132.05±30.61	131.6±32.09	0.830
10-meter walk (sec)	8.01±0.88	7.26±0.86	**0.001**	7.09±0.75	6.91±0.88	0.181
Shuttle running test (sec)	12.42±1.68	12.47±137	0.886	12.49±1.37	12.06±1.39	**0.015**
Heel raise test (rep.)	35.5±15.86	38.75±16.23	0.072	39.05±21.37	47.16±29.52	**0.012**
IPAQ (METs)	2785.3±2419.4	2450.7±1811.3	0.489	2150.3±2036.8	3010.1±2449.6	**0.017**

ROM: Range of motion, DF: dorsiflexion, PF: plantar flexion, EV: eversion, cm: centimeters, sec: seconds, MET: Metabolic equivalent of task, IPAQ: International Physical Activity Questionnaire, Paired sample t-test, p<0.05

When comparing the mean differences in pre- and post-test results between the groups, a significant difference was observed in the eversion ROM (p=0.038), inversion ROM (p=0.931), YBT (p<0.001), and SRT (p=0.045) scores, favoring the 3D-printed group. Conversely, IPAQ scores showed a significant difference in favor of the placebo group (p=0.046). No significant differences were found in the other outcome measures (p>0.05) (see Table 3).

Table 3. Comparison of 3d printed and placebo groups' pre-posttest differences

	3D printed Group (n=20)	**Placebo Group (n=18)**		
	X±SD	**X±SD**	**t**	**p**
Eversion ROM	0.43±4.07	4.76±7.49	0.876	**0.038**
Inversion ROM	-0.24±7.59	0.83±9.63	0.087	0.931
Muscle strength DF (lbs.)	1.97±3.58	1.83±4.96	0.105	0.917
Muscle strength PF (lbs.)	2.42±4.61	0.91±3.43	1.133	0.265
Muscle strength EV (lbs.)	2.60±4.56	2.94±5.19	-0.217	0.826
Flaming balance test	1.48±2.17	0.53±1.68	-1.496	0.143
Y balance test total	22.58±5.17	1.16±5.88	-11.951	**<0.001**
Standing long jump (cm)	4.05±11.91	0.38±7.57	-1.116	0.272
10-meter walk (sec)	0.74±0.82	0.53±0.61	-0.898	0.375
Shuttle running test (sec)	0.047±0.73	0.42±0.66	2.075	**0.045**
Heel raise test (rep.)	3.25±7.62	8.11±12.1	-1.490	0.145
IPAQ (METs)	334.6±2123.1	859.66±1382.8	-2.029	**0.046**

ROM: Range of motion, DF: dorsiflexion, PF: plantarflexion, EV: eversion, cm: centimeters, sec: seconds, MET: Metabolic equivalent of task, IPAQ: International Physical Activity Questionnaire, Independent sample t-test, p<0.05

DISCUSSION

In this study, which examined the effects of customized 3D printed insoles on physical activity level, balance, and functional performance in patients with pes planus, significant differences were observed in muscle strength, static and dynamic balance, and 10 MWT in the 3D printed group. In the placebo group, significant differences were observed in the normal range of motion of eversion movement, peroneal muscle strength, SRT, HRT, and physical activity levels. While the Y balance test demonstrated a significant increase in the insoles group, there was no difference between the two groups in the FBT results.

In the tests performed to evaluate the foot posture of the participants in this study, significant differences were found between the 3D printed and placebo groups in the FPI scores. It was thought that this situation might have caused the results of the study. The significant improvements in favor of the placebo group may be due to better foot posture scores. Altered foot alignment could have contributed to lower test scores in this study.

When the literature was reviewed, it was noted that studies on pes planus often included patients with both unilateral and bilateral conditions in the same study. To prevent potential discrepancies stemming from participant variation, only individuals with bilateral pes planus who met the inclusion criteria were enrolled., thus eliminating the effect of asymmetric effect on physical activity and quality of life evaluations.

While Araujo et al. stated that foot orthoses may decrease eversion by increasing afferent feedback (22), Wahmkow et al. found that this was not true in their study (23). In this study, the use of insoles for 8 weeks did not restrict eversion movement and did not increase inversion movement. The placebo group exhibited an increase in eversion movement, which is unfavorable for patients with pes planus. It was concluded that placebo insoles are not beneficial and may potentially be detrimental to patients with pes planus. The absence of medial wedge support in patients with pes planus may have led to an excessive load on the medial aspect of the foot, thereby increasing eversion. This observation suggests that pes planus could be a progressive postural disorder.

Zhao et al. conducted a study measuring ankle muscle strength in 67 men aged 40 to 64 years using an isokinetic device. They discovered a negative correlation between medial arch height and ankle muscle strength, suggesting that the adaptation of the medial arch for weight support and shock absorption influences ankle muscle strength (24). Some studies suggest that orthosis use has neuromuscular effects, and Nigg et al. developed a sensorimotor theory that orthoses may alter afferent stimuli to muscle and proprioceptive sensory endings (25). Jung et al. conducted an 8-week follow-up study involving 28 pes planus patients divided into two groups. One group received customized foot insoles, while the other received customized foot insoles along with short foot exercises. The study revealed an increase in the cross-sectional area of the abductor hallucis muscle and flexor hallucis muscle strength in both groups. However, a more substantial increase was observed in the group that incorporated exercises. (26) . Baur et al. randomly divided 99 runners aged between 18 and 60 years with overuse injuries into intervention and control groups and found that foot orthosis increased activation of the peroneal muscles before heel contact. This suggests that altered afferent input from the foot and other proprioceptive structures may contribute to ankle stability (27). However, some studies show that orthoses do not affect muscle strength (28). According to the muscle strength results of this study, a significant increase in plantar flexion and eversion forces was observed in both groups as a result of analyzing the effects of insoles. It is thought that this increase is caused by the change in afferent input and therefore has a positive effect on muscle contraction. The lack of difference between the groups supports this view. When the long-term effects of the insoles were analyzed, it was observed that the effect of increased afferent input in plantar flexion continued in the intervention group but not in the placebo group. The use of insoles may have corrected the traction angle of the Achilles tendon by positioning the foot more accurately. The reason for the increase in eversion muscle strength in the placebo group may be that the increased eversion angle requires more muscle strength to provide stability in the distal group muscles of the foot. Increased muscle strength in the inversion and eversion directions may be a compensatory effect to stabilize the foot and ankle. Increased muscle strength as a result of the use of insoles may have helped the muscle to be in the optimal position and to realize its potential.

Kuyung and Seop investigated the effect of insoles on balance performance in people with pes planus. In the study, 14 university students were randomly divided into two groups: an insoles-supported group and a short-foot exercise group. Their balance was measured with YBT and it was reported that dynamic balance increased significantly in both groups (29). They stated that the reason for the improvement in the insoles group was the decrease in maximum ground reactions and the emergence of dynamic and biomechanical effects. In this study, static balances did not improve with the use of insoles, but significantly decreased in the placebo group.

In dynamic balance assessments, significant post-test improvements were observed in both the 3D printed and placebo groups following insole use. This enhancement could be attributed to increased activity levels and alterations in ground reaction forces. However, the absence of noticeable effects of insoles in static balance tests might be attributed to proper foot alignment and inadequate stiffness of the insoles.

In a study conducted by Tudor et al. arc index and explosive power of 218 children aged between 11 and 15 years were evaluated. Kistler Quattro jumping force platform was used and it was reported that there was no relationship between arch height and explosive power (30). In this study, no significant change was observed in explosive power nor the post-test scores. This may be due to the fact that jumping involves complex movements that are not only related to plantar flexion muscle strength. Therefore, according to the results of the study, it is thought that explosive strength cannot be related to muscle strength alone and more factors should be considered to make a significant difference in jump performance.

In a study conducted on healthy young adults, Okunuki et al. examined the effect of increased pronation in the hindfoot on physical performance. In that study, performance tests such as the shuttle running test were used and it was observed that the results of the shuttle running test deteriorated with an increasing degree of pronation in the hindfoot (31). Other studies have also indicated that foot orthoses and shock-absorbing insoles may affect running ergonomics and the mass of the insoles should also be considered (32-34). Researchers have reported that insoles may not have an immediate effect on running performance, but 8 weeks of use may affect performance (34). In this study, it was observed that the insoles in the placebo group outperformed those in the 3D printed group. Possible reasons for this disparity may include initial discomfort and an adaptation process associated with the insoles' use. Consequently, the utilization of insoles might have altered habitual foot positioning and the distribution of tasks among lower extremity muscles, potentially leading to new foot positioning and discrepancies in workload distribution among lower extremity muscles.

The study investigated the impact of shoe usage on the heel elevation test and revealed no significant difference between the test results conducted with or without shoes (35). In our study, we observed an increase in the number of repetitions during the HRT as a result of insole usage, although no significant difference was found between the groups. However, after 8 weeks, a significant increase in repetitions was noted in the placebo group, whereas no such difference was observed in the 3D printed group. We hypothesized that the immediate effect of the insoles was manifested through enhanced plantar flexion muscle strength. Additionally, the participants in the 3D printed group may not have exhibited improvements in test results due to arch supports causing discomfort. Furthermore, the extent of insole usage over the 8 weeks was not documented, raising the possibility that the insoles may not have been sufficiently effective in improving the muscle endurance of the participants.

Lopez-Lopez et al. conducted a study investigating the relationship between arch height and quality of life and reported that there was no significant difference between arch height and physical activity (36). Wrobel et al. conducted a study in which they reported that customized insoles improved physical activity levels compared to prefabricated and placebo insoles (37). However, in this study, it was thought that the insoles might have caused foot discomfort among participants in the 3D printed group, potentially leading to reduced participation in physical activity. This suggests that discomfort in patients with pes planus may increase the possibility of rejection and disuse of insoles. It is thought that the increase in the level of physical activity in the placebo group may also be due to the psychological effects of insoles and that people may have participated in more activities by feeling safer with insoles.

LIMITATIONS

All of the participants used insoles with the shoes they most frequently wore. In this study, participants participated in different types of footwear such as shoes, trainers, and boots. It was thought that participation in future studies with a single type of shoe would yield more accurate results. The inability to categorize participants based on the severity of pes planus may have influenced the study outcomes. Comparing patients with similar degrees of pes planus could potentially yield more robust results. Additionally, the fatigue levels of study participants were not assessed before evaluation, and fatigue levels may impact physical activity scores.

CONCLUSION

The utilization of customized 3D insoles in patients with pes planus led to enhancements in muscle strength, dynamic balance, and muscle endurance of the tibialis posterior muscle, and affected the level of physical activity. The improvements observed in the 3D printed group are believed to stem from increased sensory input from the sole and proper foot biomechanics. Conversely, enhancements in the placebo group are attributed to psychological effects and increased levels of physical activity.

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