STUDY DOCUMENT COVER PAGE

Study Title:

The Effects of Custom-Designed 3D Printed and CAD-CAM Insole on Foot Posture, Plantar Pressure Distribution and Satisfaction in Individuals with Flexible Pes Planus

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Study Location: Ondokuz Mayıs University, Department of Orthotics and Prosthetics, Samsun, Turkey

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Study Title

The Effects of Custom-Designed 3D Printed and CAD-CAM Insole on Foot Posture, Plantar Pressure Distribution, and Satisfaction in Individuals with Flexible Pes Planus

Study Purpose and Importance

The purpose of this study is to investigate the effects of custom-designed insoles manufactured using Computer Numerical Control (CNC) and 3D printing technologies on plantar pressure distribution, foot posture, plantar force distribution, foot pain, and satisfaction in individuals diagnosed with flexible pes planus. This research aims to contribute to evidence-based practice in orthotic interventions.

Study Site

The study will be conducted at the Orthotics and Prosthetics Application and R&D Laboratories of the Faculty of Health Sciences at Ondokuz Mayıs University.

Study Period

The study will be carried out between **April 1, 2025** and **December31, 2025**.

Study Design

This study will be conducted as a randomized controlled trial.

Study Population and Sample

The study population consists of individuals aged between 18 and 55 who have been clinically diagnosed with flexible pes planus and referred with a physician's prescription for custom insoles to the Orthotics and Prosthetics Department at Ondokuz Mayıs University.

Sample size was calculated using the G*Power 3.1.9.4 software. Based on the study by Ünver and Bek (2014) that investigated the effects of insole use on plantar contact area and pressure distribution, with an alpha of 0.05, an effect size of 1.53, and a power of 0.95, the required sample size was determined to be 13 individuals per group, for a total of 26 participants. To increase statistical power and account for potential dropouts, the study will include 40 participants, divided equally into two groups (20 in each).

Inclusion Criteria

Age between 18 and 55

Diagnosed with unilateral or bilateral flexible pes planus

At least +6 on the Foot Posture Index (FPI)

≥5° subtalar pronation angle during standing

No foot or lower limb treatment in the last 6 months

Voluntary participation with written and verbal informed consent

Exclusion Criteria

History of lower extremity surgery

Active athlete status

Pregnancy or malignancy

Neurological or orthopedic conditions limiting physical activity

More than 1 cm lower limb length discrepancy

Receiving any other treatment for pes planus

Randomization and Groups

Participants will be randomly assigned to one of two groups using a simple randomization method (drawing lots).

Group 1 will receive insoles produced using CNC technology.

Group 2 will receive insoles produced via 3D printing.

Each participant will be evaluated before and after 8 weeks of insole use.

Data Collection Tools and Assessment Methods

Participants will be evaluated at baseline and after 8 weeks of insole use. The following tools will be used:

Foot Posture Index (FPI): Assesses the degree of pes planus; individuals scoring +6 or higher are eligible.

Subtalar Angle Measurement: Conducted with a goniometer while standing barefoot.

VAS-FA (Visual Analog Scale – Foot and Ankle): Evaluates pain and functional limitations specifically related to the foot and ankle. The scale ranges from worst to best function and pain levels, based on participant self-reporting.

Plantar Pressure Analysis: Using a sensor-based platform for both static and dynamic measurements of plantar contact and pressure distribution.

Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0): Measures user satisfaction with the orthotic device.

Orthotics and Prosthetics Users' Survey (OPUS) – Lower Extremity Functional Scale: Evaluates lower limb functionality and daily mobility performance.

Data Collection Procedure

Each participant's group will be determined by random draw.

- 20 participants will receive CNC-produced insoles.
- 20 participants will receive 3D-printed insoles.

Data will be collected through:

- Face-to-face administration of surveys
- Pressure mapping via pedobarographic analysis
- Standardized clinical measurement protocols

Statistical Analysis

Statistical analysis will be conducted using **IBM SPSS 22**. Descriptive statistics (mean ± SD) will be used for demographic and clinical variables.

- **Normality testing**: Shapiro-Wilk test
- **Within-group comparisons** (pre- and post-intervention): Paired t-test
- **Between-group comparisons**: Independent samples t-test
- **Repeated measures** (time × group interaction): Repeated Measures ANOVA
- **Categorical variables**: Chi-square and Fisher's Exact Test

A significance level of **p < 0.05** will be considered statistically significant.

Informed Consent Form

Study Title:

The Effects of Custom-Designed 3D Printed and CAD-CAM Insole on Foot Posture, Plantar Pressure Distribution, and Satisfaction in Individuals with Flexible Pes Planus

Dear Participant,

You are invited to take part in a scientific study titled "The Effects of Custom-Designed 3D Printed and CAD-CAM Insole on Foot Posture, Plantar Pressure Distribution, and Satisfaction in Individuals with Flexible Pes Planus," conducted by the Department of Physiotherapy and Rehabilitation at Lokman Hekim University.

This study aims to examine the effects of custom-made insoles produced with Computer Numerical Control (CNC) and 3D printing methods on foot posture, plantar pressure distribution, foot pain, and user satisfaction in patients diagnosed with flexible pes planus.

You will be provided with a custom-designed insole. You are expected to use it regularly for 8 weeks. These insoles are not associated with any side effects. Your honest participation and answers will help determine which insole model is more effective, and may contribute to improvements in future orthopedic practices.

Voluntary Participation and Confidentiality

Participation in this study is completely voluntary. You may refuse to participate or withdraw at any time, without any consequences or loss of rights.
Your personal information will remain confidential and will be used only for scientific purposes. Your name will not appear in any reports or publications resulting from this research.

Evaluation Process

You will be asked to complete several questionnaires and undergo evaluations at the beginning and at the end of the 8-week insole usage period. Each session will take approximately 30 minutes.

You are expected to:

- Wear the insole regularly
- Answer all the questions sincerely
- Attend both evaluation sessions

Contact Information

If you have any questions or concerns regarding the study, you may contact the following researchers:

Principal Investigator:

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Consent Statement

☐ I have read and understood the information above. I voluntarily agree to participate in this study.

Participant
Name & Surname: .....
Signature: .....
Date: ___ / ___ / 2025

Witness (if needed)
Name & Surname: .....
Signature: .....

Researcher
Name & Surname: .....
Signature: .....