Clinical Biomechanics 122 (2025) 106423

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Effect of different custom-made foot orthotics on foot joint stiffness in individuals with structural hallux limitus: A quasi-experimental study

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ARTICLE INFO

Keywords:
Custom-made foot orthotics
Joint stiffness
Structural hallux limitus

ABSTRACT

Background: Normal dorsiflexion of the first metatarsophalangeal joint during dynamic activities is critical for effective propulsion. Therapeutic foot orthotics may address the pathomechanical loading and joint kinematics issues faced by this population. This study aims to evaluate the effect of two different types of Custom-made foot orthosis compared to shod condition on the stiffness of the rearfoot, midfoot, and 1st metatarsophalangeal joint during walking in patients with Structural Hallux Limitus.

Methods: This quasi-experimental study used a repeated-measures design with a single cohort. 24 participants with structural hallux limitus were sampled. Two custom-made Foot Orthotics – a cut-out and an anterior forefoot stabiliser element – were compared under three conditions using minimalist SAGURO neoprene shoes: shod, shod with cut-out custom-made foot orthosis, and shod with anterior forefoot stabiliser element foot orthosis. Kinematic data were captured using a modified Bruening model. We examined the variable stiffness (quantified in Nm/Kg/rad).

Findings: Significant differences were found in dynamic stiffness only between Anterior forefoot stabiliser element custom-made foot orthosis, and the patient shod during the propulsion phase at the 1st Metatarsophalangeal joint ($R^2 = 0{,}07$ $p = 0.027$) and a difference of 0,86 Nm/kg/rad. No significant differences were observed for dynamic stiffness in any other phase of the stance period across all conditions.

Interpretation: The Anterior forefoot stabiliser element, in particular, significantly increases the stiffness of the 1st Metatarsophalangeal joint compared to walking shod.

1. Introduction

Hallux limitus (HL) refers to osteoarthritis of the first metatarsophalangeal joint (1st MTPJ), leading to restricted dorsiflexion in the sagittal plane. HL affects 1 in 40 adults over the age of 50, although younger individuals may also be affected (Fung et al., 2020). The medical community identifies two forms of hallux limitus (HL): structural hallux limitus (SHL) and functional hallux limitus (FHL). In SHL, restricted motion is observed in both loaded and unloaded conditions, whereas in FHL, the limitation occurs only when the foot is weight-bearing (Clough, 2005; Dananberg, 1986). Biomechanical consequences of HL include compensatory adjustments in other joints, such as increased ankle dorsiflexion, reduced plantarflexion, and altered knee flexion, which disrupt gait mechanics and may contribute to postural

Abbreviations: First metatarsophalangeal joint, 1st MTPJ; Foot orthotics, FO; Custom-made foot orthotics, CFOs; Anterior stabiliser element, AFSE; Structural Hallux Limitus, SHL; Hallux Limitus, HL; Foot Posture Index, FPI; Metatarsophalangeal, MP; Midtarsal, MT; Ethylene-vinyl acetate, EVA.

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https://doi.org/10.1016/j.clinbiomech.2024.106423
Received 28 May 2024; Accepted 16 December 2024
Available online 25 December 2024

changes(Canseco et al., 2012). These changes are associated with pain and may lead to chronic alterations over time, though further empirical evidence is needed to confirm this progression. HL is known to significantly impact lower limb function, affecting overall movement efficiency and potentially increasing the risk of long-term musculoskeletal complications(Zammit et al., 2009).

Treatment modalities for HL typically encompass a range of non-surgical approaches, including functional taping, exercises and manipulations (Caravelli et al., 2018; Colò et al., 2020; Munuera Martínez, 2008; Shamus et al., 2004). Another valuable therapeutic intervention is the application of foot orthotics (FO) since it is hypothesized that these medical devices may address the (mal)adaptive pathomechanical loading and foot joint kinematics that this population is facing (Welsh et al., 2010). For individuals with HL, a common treatment involves using a foot orthotics (FO) with a medially placed wedge to manage external pronatory forces, which can affect foot alignment and biomechanics. A common design for patients with HL is the cut-out FO. This design features a cut-out over the first metatarsal head. Some researchers also incorporate an extension at the hallux, referred to as a dynamic wedge extension, along with this cut-out. Studies indicate this FO design increases plantarflexion of the first ray(Becerro de Bengoa Vallejo et al., 2016), enabling dorsiflexion of the proximal phalanx over the metatarsal head. This reduces joint compression during propulsion and decreases adduction of the first metatarsal (De Bengoa Vallejo et al., 2016; Menz et al., 2016). However, evidence about the therapeutic efficacy of these FO remain scarce and more importantly, there is poor insight into the real drivers behind these foot joint pathomechanics.

The study of joint stiffness has become crucial in biomechanics for assessing the mechanical properties of lower limb joints (Sanchis-Sales et al., 2016; Zammit et al., 2009). Literature on stiffness of foot joints other than the ankle is limited due to the complexity of assessment. However, studying stiffness in other foot joints, like the 1st MTPJ, could offer valuable insights. Reduced mobility in this joint affects other body joints, making it essential to design effective treatments or shoes (Munteanu et al., 2021). A deeper understanding of joint stiffness may improve the design of foot orthotics and prostheses (Sanchis-Sales et al., 2016).

This study aimed to evaluate the effect of two types of custom-made foot orthotics (CFO) (AFSE CFO and cut-out CFO), defined as manually made orthotics adapted to the patient's foot, compared to a shod condition, on ankle, midfoot, and 1st MTPJ stiffness during walking in SHL patients.

2. Materials and methods

2.1. Study design

This quasi-experimental study used a repeated-measures design with a single cohort. Each participant was randomly evaluated across three different conditions: 1) shod without a CFO, 2) shod with a cut-out CFO and 3) shod with a AFSE CFO.

2.2. Participants

Recruitment took place at the University of San Jorge, sports clubs, and a private clinic from October 2021 to December 2022. Twenty-four individuals with painless SHL participated, with an average age of 34.2 years (±7.9), a Body Mass Index (BMI) of 23.9 kg/m^2 (±2.6), heigh 169 (±7.4), weigh 69.5(±9.3) and size shoe 40.5 ± 2.2(European size). Inclusion criteria were: (1) age 18–65 years, (2) clinical diagnosis of SHL measured with a goniometer in a non-weight bearing condition showing less than 60 degrees of motion (López del Amo Lorente et al., 2013; Munuera Martínez, 2008; Toboadela, 2007)(3) positive Jack's test (Gatt et al., 2014), (A positive Jack test was defined as the absence of one or more of the three movements described in the test when dorsiflexing the first toe: arch elevation, hindfoot inversion, or external tibial rotation. It was also considered positive when there was significant resistance to dorsiflexion of the toe, even if one or more of the aforementioned movements occurred) (4) positive lunge test (resulting in negative scores (knee to wall distance) and positive scores (toe to wall distance)) (Bennell et al., 1998), and (5) Foot Posture Index (FPI) over 6 (patient with pronated feet) (Redmond et al., 2008). Participants were asymptomatic to avoid possible compensation mechanisms caused by the present symptomatology and the diagnosis was determined clinically, without radiographs.

Exclusion criteria included (1) patient with neurological, systemic, or orthopedic conditions, (2) patient with pain, (3) who suffered foot or lower limb trauma, (4) or who were unable to walk unassisted.

The clinical assessment was performed always by the same professional, a trained professional with several years of experience.

The study followed the Declaration of Helsinki's ethical standards and received approval from the University of Malaga's Ethics Committee (CEUMA-12-2021-H). Informed consent was obtained from all participants.

2.3. Intervention

Two types of CFOs were provided. The first type, integrating an Anterior Forefoot Stabiliser Element (AFSE-CFO)(Fig. 1a), was made using a direct molding process with a vacuum forming machine. It featured a rocker shape extending from the metatarsal heads to the toes, using polyester resin as the primary material. The construction involved layers of 1.2 mm podiaflex and podiaflux for the rearfoot and midfoot, and 0.8 mm podiaflex for the forefoot, completed with a 30 shore A and 148 kg/m^3 density PE-EVA shell using the same protocol of Martinez-Rico et al. (Martinez-Rico et al., 2024).

The second foot orthotics, the Cut-out CFO, was produced via 3D printing using HP multijet fusion (Fig. 1b). A digital volumetric anatomical model of each participant's feet was generated using a Structure Sensor (Occipital Inc., Boulder, CO) in conjunction with acquisition software from TechMed3D (3D Size Me app, Lévis, QC). The system included three cameras, an integrated inertial measurement unit (IMU), and a NU3000 processor, providing a depth resolution of 1280 × 960, The system has an accuracy of approximately ±1 mm in measuring the depth and anatomical contours, which aligns with current standards for clinical applications in podiatry and orthotic design. The design, processed in Rhino 3D and Rhino 6, featured full contact medial arch support and a cut-out at the first metatarsal head, with a 1 mm EVA extension under the hallux. This orthotics was made using Polyamide 12 (PA 12) for the shell, complemented by PE-EVA for the forefoot stabilizing element and the top cover.

Additionally, we can clarify that the orthoses (FO) were personalized for each participant based on shoe size, ensuring that length and width were proportionate to each individual's foot measurements used the

Fig. 1a. Anterior Forefoot Stabiliser Element Fig. 1b. CFO with first metatarsal head cut-out.

proposal of Gijon-Nogueron et al.(Gijon-Nogueron et al., 2015).

2.4. Gait evaluation

Gait analysis involved recording joint kinematics and ground reaction force using a pressure platform. The study adapted a model by Bruening et al. (Bruening et al., 2012; Sanchis-Sales et al., 2016) to capture the kinematics of the ankle, midfoot, and 1st MTPJ, segmenting the foot into three parts: rearfoot, midfoot, and hallux. Twenty reflective markers were placed on anatomical reference points on the leg and foot. To ensure accuracy, shoes were trimmed so markers aligned with anatomical landmarks, avoiding movement caused by the fabric. The 3D motion of markers was tracked using an eight-camera infrared system (Vero, Vicon® Motion Systems Ltd., UK) at 100 Hz. Joint angles were computed using the Cardan rotation sequence, starting from a static reference pose and expressed as a percentage of the stance phase. Simultaneously, a Podoprint pressure platform (Namrol, Barcelona, Spain) measured pressure distribution in sync with the motion capture system. The synchronization between both systems was based on the minimum height of the C1 marker during the heel contact phase, which was synchronized with the first moment when pressures appeared on the platform.

Participants walked at a comfortable pace on a pressure platform (0.40 × 0.40 m, 4 mm thick, 0.15 mm sensor) centrally positioned. Data collection followed a 3-step protocol (Bruening et al., 2018) with a 10-min acclimation period, ensuring consistent gait across conditions. Each patient was measured while wearing minimalist SAGURO neoprene shoes (to ensure compatibility with different orthotics and minimal interference with foot biomechanics) and this throughout 3 conditions: shod, shod with cut-out CFO and shod with AFSE CFO. Each condition was assigned randomly to each participant.

The identification of gait phases and the calculation of stiffness were performed following the protocol described by (Sanchis-Sales et al., 2016), the dynamic stiffnesses were computed as the slopes of the linear regressions at those phases where the dorsiflexion moment-angle relationship was approximately linear: early midstance and propulsion for the ankle (K^{EMSP} and K^{PP}), late midstance stance and propulsion for the midtarsal joint (K^{LMSP} and K^{PP}) and propulsion for the metatarsophalangeal joint (K^{PP}). Nm/Kg/rad" represents the torque (in Newton-meters) required for an angular deformation (in radians) normalized by body mass (in kilograms). In SI terms, this can be expressed as: Nm/Kg/rad = (kg\cdotpm2/s2)/(kg) = m2/s2. Phases were trimmed by 5 % at both the onset and ending of each phase, and then the dynamic stiffness was calculated as the slope of the linear regression of the joint moment versus the joint angle, i.e. the tangent of the angle from the horizontal to the interpolated straight line. However, the tangent function is non-linear and presents a dis- continuity at 90°, which may introduce errors when calculating mean values and when applying ANOVAs. To avoid these problems, mean calculations and ANOVAs were performed directly on the angles (θ), and results were finally transformed into dynamic stiffness data by computing the tangent of the angle data.

A total of ten walking trials were recorded and the five trial with the highest visibility and the fewest instances of marker loss (minimal gaps in the data) were selected for further analysis.

2.5. Statistical analysis

The mean joint 3D rotations and joint moments throughout the stance phase of gait were compared between conditions using a one-dimensional statistical parametric ANOVA applied to the extracted parameters of the curves (not to the curves themselves). This method allowed us to analyze the effects of the different conditions (shod, shod with cut-out CFO, and shod with AFSE CFO) on joint kinematics and stiffness across specific time points within the stance phase. Assumptions of sphericity and normality were checked, and corrections were applied where necessary to ensure the validity of the statistical comparisons. A *p*-value of <0.05 was considered statistically significant.

3. Results

The mean non-weightbearing dorsiflexion of the participants was 42° (± 7.7°). Fig. 2 shows the plots of joint dorsiflexion external moments versus joint dorsiflexion angles during the stance phase, averaged across all repetitions and participants. The lowest linearity observed was during the propulsion phase at 1st MTPJ, although R^2 values were still above 0.97. Dynamic stiffness was greater for AFSE CFO feet in all phases and joints, except in the early midstance phase at the ankle.

Statistical data for dynamic stiffness in different phases are reported, with significant statistical differences shown in Table 1.

Significant differences were found only between AFSE CFO and shod during the propulsion phase at the 1st MTPJ. No significant differences were observed for dynamic stiffness in any other phase of the stance period across all conditions.

4. Discussion

The objective of this brief study was to evaluate the effect of two different types of CFO (AFSE CFO and cut-out CFO) compared to shod condition on the stiffness of the ankle, midfoot, and 1st MTPJ during walking.

The results show an increase in joint stiffness with both CFOs. AFSE CFO show a difference of 0,7 Nm/kg/rad compared to shod at ankle in the propulsion phase.

With respect to midfoot, a difference of 2,58 Nm/kg/rad 2,1 Nm/kg/rad is observed with AFSE CFO and cut-out CFO respectively, compared to shod in the propulsion phase too.

However, the only difference that was statistically significant was ($p = 0.027$) found between AFSE and shod at 1st MTPJ in the propulsion phase, with a difference of 0,86 Nm/kg/rad.

It is evident that walking without CFO results in lower stiffness; that is, the introduction of an CFO increases foot rigidity, particularly in the 1st MTPJ. This increased rigidity might be attributed to reduced movement of the feet when foot CFOs are used. Thus confirming the hypothesis put forward at the beginning of the study.

Regarding pronated feet and FHL, we acknowledge that the evidence linking pronated feet to FHL is not definitive (Zammit et al., 2009). However, our study involved patients with SHL, which has been associated with pronated feet (Durrant and Chockalingam, 2009).The increase in foot rigidity we observed in these patients could potentially improve functional performance, as a stiffer foot enhances energy efficiency during propulsion (Sanchis-Sales et al., 2016). While our findings are consistent with this mechanical framework, further studies are needed to clarify the exact impact on first MTP joint osteoarthritis symptoms.

In patients with neurological conditions, increased stiffness enhances energy efficiency, improving gait (Anderson et al., 2024; Waterval et al., 2024). For diabetic patients, however, the aim is often to reduce stiffness to ensure comfort and adaptation of the foot with respect to the ground (Jafarzadeh et al., 2021; Shaulian et al., 2023). Few studies have analyzed foot joint stiffness in patients without neurological conditions, such as in our case, where excessive pronation or mechanical rigidity deficiency in the 1st MTP joint can improve propulsion, as widely observed in running techniques (Barton et al., 2009).

The use of an element like the AFSE CFO can provide sufficient mechanical stiffness for patients with SHL, improving their propulsion phase and better compensating for the associated pronation typical of these patients. This represents an advancement in the treatment of this pathology.

Our findings indicated that stiffness is always greater with CFO, but significant differences were only observed between AFSE CFO and shod conditions. It is important to note the limitations of this study. One

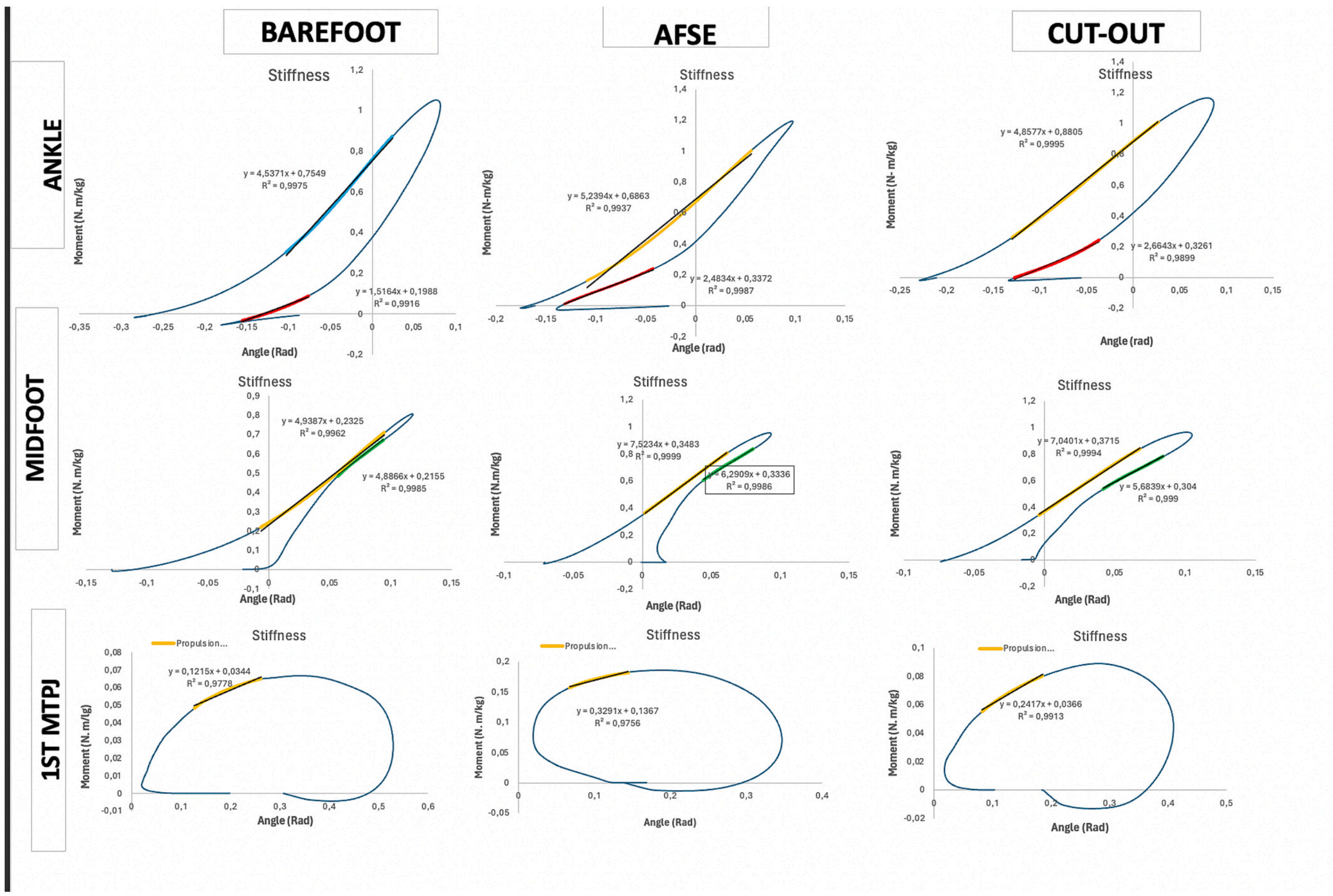

Fig. 2. Mean dorsiflexion moment versus dorsiflexion angle at the ankle, midtarsal (MT) and 1st MTPJ, averaged throughout all of the repetitions and participants. The values of the dynamic stiffnesses during the early midstance, late midstance and propusion phases are calculated.

Table 1
Mean (SD) values, for each condition, for the dynamic stiffness in the different phases considered: early midstance phase (EMSP), late midstance phase (LMSP) and propulsive phase (PP) And Summary of the results from the ANOVAs performed to identify the effect of the condition on the dynamic stiffness at the different phases considered.

Joint_Phase	Phase	SHOD (Mean/SD)	AFSE cfo(Mean/SD)	CUT-OUT cfo (Mean/SD)	Comparison	p_value
REARFOOT (Nm/Kg/rad)	Early midstance	1.52(0,24)	2.48(0,39)	2.66(0,54)	Shod vs. AFSE CFO	0.169
					Shod vs. Cut-out CFO	0.191
					AFSE CFO vs. Cut-out CFO	0.811
	Propulsion phase	4.54(0,53)	5.24(0,45)	4,86(0,87)	Shod vs. AFSE CFO	0.419
					Shod vs. Cut-out CFO	0.782
					AFSE CFO vs. Cut-out CFO	0.735
Midfoot (Nm/Kg/rad)	Late midstance	4.89(1.71)	6.29(2.02)	5.68(1.91)	Shod vs. AFSE CFO	0.649
					Shod vs. Cut-out CFO	0.785
					AFSE CFO vs. Cut-out CFO	0.847
	Propulsion phase	4.94(0.87)	7.52(1.57)	7.04(1.82)	Shod vs. AFSE CFO	0.286
					Shod vs. Cut-out CFO	0.407
					AFSE CFO vs. Cut-out CFO	0.859
1st MTPJ (Nm/Kg/rad)	Propulsion phase	0.12(0,04)	0.98(0,14)	0.24(0,19)	Shod vs. AFSE CFO	**0.027**
					Shod vs. Cut-out CFO	0.596
					AFSE CFO vs. Cut-out CFO	0.089

limitation is the sample size. Additionally, it may be important to evaluate how different materials used in the construction of CFO affect stiffness. In this study, both types of CFOs were made from materials considered rigid, unlike others such as ethylene-vinyl acetate (EVA) or rubbers, which might yield different results. In addition, patients with pronated feet, and no pain were studied, so it would be advisable to investigate individuals with other foot morphologies, such as cavus or neutral feet, or patients experiencing pain. Moreover, we only examined the short-term effect, so it is unclear whether the results would be similar in the long term. Although the custom foot orthosis can be used outside the study, further research with a larger sample size is necessary to generalize the findings.

Moreover, it is worth considering the implications of these findings for clinical practice. For patients with SHL and similar conditions, selecting an appropriate CFO that enhances foot rigidity could be crucial for improving their gait and overall mobility. Future studies could also explore the long-term effects of using such CFO on foot health and patient comfort, providing a more comprehensive understanding of their benefits and potential drawbacks. Additionally, investigating the biomechanical changes induced by different CFO designs could help in customizing treatments for various patient needs, ensuring both functionality and comfort.

5. Conclusion

In conclusion, this study provides insight into the role of CFO in altering foot rigidity. The AFSE CFO, in particular, significantly increases the stiffness of the 1st MTP joint compared to walking shod. This increase in rigidity may enhance energy efficiency, particularly in patients with SHL, by compensating for excessive pronation. Future research should focus on larger sample sizes and the impact of different CFO materials to further understand the implications of CFO stiffness on foot mechanics and overall gait efficiency. Such studies will be instrumental in optimizing CFO designs for specific patient populations, ultimately improving clinical outcomes and patient quality of life.

Funding

Funding for open access charge is provided by Universidad de Malaga/CBUA.

CRediT authorship contribution statement

Magdalena Martinez-Rico: Writing – review & editing, Writing – original draft, Data curation, Conceptualization. **Gabriel Gijon-Nogueron:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Ana Belen Ortega-Avila:** Writing – review & editing, Conceptualization. **Luis Enrique Roche-Seruendo:** Writing – review & editing, Data curation. **Ana Climent-Pedrosa:** Data curation. **Kevin Deschamps:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Enrique Sanchis-Sales:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Conceptualization.

Declaration of competing interest

None.

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