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The Direct Impact Effect of Different Foot Orthotic Designs on the Plantar Loading of Patients with Structural Hallux Limitus: A Quasi-Experimental Study

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Abstract: Background: This study examines the effect of two types of custom-made foot orthoses (CFOs) in patients with structural hallux limitus (SHL). Methods: In this quasi-experimental, repeated measures study, 24 participants with SHL were sampled. Two CFOs—cut-out CFO and anterior stabilizer element (AFSE) CFO—were compared using minimalist SAGURO neoprene shoes: no foot orthoses (FO), cut-out CFO, and AFSE CFO. Plantar pressures and center of pressure (CoP) displacement were measured using a Podoprint® platform. Results: Both CFOs shifted the CoP medially during midstance ($p < 0.001$ with AFSE CFO and $p = 0.0036$ with cut-out CFO). The AFSE CFO showed a more anterior CoP in midstance, while the cut-out CFO affected anterior CoP in midstance and pre-swing. The AFSE CFO significantly increased pressure in the second toe, lesser metatarsal heads (MTH), midfoot, and rearfoot. In contrast, the cut-out CFO decreased pressure in the second MTH and lesser toe regions, increasing pressure in the midfoot and heel. Both CFOs lowered the hallux/first MTH ratio compared to shod without CFO. Conclusions: The cut-out CFO led to medial and anterior CoP displacement, reducing lateral foot and hallux pressure while transferring loads to the first MTH. The AFSE CFO caused a similar shift by increasing loads on the first MTH.

Keywords: hallux limitus; treatment; foot orthosis; plantar pressures; center of pressure

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1. Introduction

How does the use of foot orthoses affect plantar pressure distribution in patients with hallux limitus? Hallux limitus (HL) is a common foot condition characterized by restricted sagittal plane motion of the hallux, where the range of motion is less than 65 degrees [1,2]. It affects an estimated 1 in 40 adults over the age of 50, although younger individuals may also be affected [3]. The prevalence of the disease varies according to the age of, and the risk factors associated with, each person (arthritis, biomechanical overloads, etc.) [4]. This condition can significantly impair mobility, making early detection and management crucial for preventing further complications.

The clinical community distinguishes two types of HL: structural HL (SHL) and functional HL (FHL). In SHL, the motion restriction occurs both in a loaded and unloaded foot, while in FHL, the restriction is only present when the foot is weightbearing [4–6].

This foot condition may have multiple etiologies [7,8], however, in the case of an FHL, authors are pointing towards excessive pronatory forces across the joints of the rearfoot and midfoot affecting first ray function during propulsion [4]. Symptoms of HL, which may start mild, typically worsen over time. These symptoms include pain in the first metatarsophalangeal joint (MTPJ), paresthesia around the hallux, and changes in plantar loading during dynamic activities [1].

Understanding the distribution of plantar pressures is crucial in the evaluation of foot function during gait, as it provides valuable insights into how structural changes or pathologies affect the foot and ankle during dynamic activities such as walking [9]. The measurement of plantar pressures offers the ability to detect pathological patterns associated with various foot conditions, which in turn helps in diagnosing and treating them. The typical trajectory of the center of pressure has been established in healthy individuals [10], but deviations from this trajectory are often seen in patients with structural or biomechanical alterations of their foot [11–13]. Therefore, studying plantar pressures is essential, not only for understanding foot biomechanics, but also for identifying characteristic patterns associated with specific pathologies.

Numerous studies have indicated that patients with HL exhibit altered plantar pressure distribution [5,14–19]. Previous research has shown that areas with higher pressures may lead to dermatological conditions such as the development of plantar callus or hyperkeratosis [19]. This alteration causes pain in patients due to overloading.

Despite many patients reporting symptoms related to plantar overloading, such as metatarsalgia and plantar callus formation, the distribution of plantar pressure in patients with HL has not received as much attention compared to other forefoot conditions. The few studies that assessed the plantar pressure distribution reported an increase in the peak pressure and loading rate under the hallux and the central metatarsal heads (MTH) [18]. However, one study also reported increased peak pressures in the rest of the toes as well [14]. Because of these alterations, a reduced weight-bearing of the first MTH has been reported [18].

In the case of mild to moderate HL, therapists often apply conservative treatments, including functional taping [8], exercises, and manipulations [20,21]. Other conservative treatments include footwear modifications [20,22] and (custom-made) foot orthoses (CFO). Through their geometric features and material characteristics, foot orthoses (FO) may either aim to restore the loadbearing function of the first ray and hallux or redistribute the forces over a bigger surface [8,22–24].

A popular FO design feature used in patients with HL is the cut-out FO [16,25–28]. This design includes the fenestration of the head of the first metatarsal head. Some authors, in addition to this fenestration, add an extension at the level of the hallux (known as dynamic wedge extension). The few studies that evaluated the efficacy of this FO design reported an increased plantarflexion of the first ray [16,27]. This plantarflexion allows the proximal phalanx to dorsiflex over the metatarsal head, generating a decrease in joint compression (especially during the propulsion phase) [26] as well as decreasing adduction of the first metatarsal [27]. The effect that these cut-out FO have on the plantar pressure distribution is much less understood since there is contradictory evidence in the literature [16,25,26]. Gombau et al. [16] reported an increase in pressure at the first MTH and a decrease on the first toe, whereas Menz et al. [26] reported a decrease in peak pressure at the first MTH as well as on the heel, and an increase in pressure at the midfoot and lesser toes.

In combination with the cut-out FO, other geometric features have been used. This may include the application of an anteriorly placed rocker element at the forefoot (e.g., Anterior Forefoot Stabilizer Element (AFSE)) or the use of a frontal plane wedge. The AFSE featured a rocker-shaped anterior portion extending from the metatarsal areas to the toes that aims at facilitating the range of motion of the first MTPJ, reducing joint pressures and therefore optimizing the load transfer between the first MTPJ and the hallux. Frontal plane wedges, aim at reducing the external pronatory moments in patients with pronated feet and is therefore a popular approach in patients with FHL [29,30]. However, the efficacy of these FO still remains unexplored.

Given the variability in plantar pressure distribution reported in previous studies and the lack of clarity on the most effective FO designs for patients with HL, the aim of this study is to compare the effects of two distinct FO geometries on plantar pressure distribution in patients with SHL, contributing to a better understanding of how to improve conservative management strategies for this condition. The main hypothesis is that both CFOs will cause a change in the distribution of plantar pressures. The cut-out CFO will have a greater effect at the level of plantar pressures while the AFSE CFO will have a greater effect at the COP, due to the design of both orthoses.

2. Materials and Methods

2.1. Design

We performed a quasi-experimental study including a repeated measure design with one study population. Each condition was randomly assigned using block randomization and implemented through SPSS software (v.29) to ensure balanced group allocation. This method was employed to minimize potential biases and maintain equal distribution of participants across all conditions. The participants were measured across three different conditions: (1) shod without a FO, (2) shod with a cut-out CFO, and (3) shod with a AFSE CFO.

2.2. Participants

A convenience sample of 24 participants (age of mean 34.2 $\pm$ 7.9 years, BMI 23.9 $\pm$ 2.6) with SHL participated in this study. Recruitment occurred at the University of San Jorge, in a private clinic, and in sports clubs all around the city from October 2021 to December 2022.

The inclusion criteria were (1) patients between 18 and 65 years, (2) the presence of SHL (<60° measured with a goniometer in a non-weightbearing state), (3) a positive jacks test [31], (the following will be taken as values: resistance when raising the finger, no receation of the foot arch), (4) a positive lunge test [32] (resulting in negative scores (knee-to-wall distance) and positive scores (toe-to-wall distance)), and (5) a pronated foot posture index (FPI) > 6. The exclusion criteria were (1) patients with neurological, systemic, or orthopedic conditions, (2) who suffered trauma to the foot and lower limb before the study, (3) or who were unable to walk without a walking aid.

This study conforms to all the STROBE guidelines [33] and reports the required information accordingly (see Supplementary Checklist). This study was carried out in full accordance with the provisions of the Declaration of Helsinki [34] regarding ethical principles for medical research involving human subjects and was approved by the Ethics Committee of the University of Malaga (CEUMA-12-2021-H), and all the patients provided a signed informed consent document.

2.3. Intervention

Each participant received two different CFOs. The first CFO was designed through a direct molding technique, using a vacuum-forming machine while directly integrating an Anterior Forefoot Stabilizer Element (AFSE CFO) with the subtalar joint in a neutral position. This forms the rocker-shaped anterior part of the orthosis which extends from the metatarsal areas to the toes. The material used to make the orthosis was polyester resin with a combination of 1.2 mm podiaflex and 1.2 mm podiaflux (Podiatech) for the rearfoot and midfoot (CSE) and 0.8 mm podiaflex for the forefoot and, as shell, a 30 shore A and 148 kg/m^3 density polyethylene–ethylene–vinyl–alcohol (PE-EVA) (Figure 1a).

Figure 1. (**a**) Plantar view of Anterior Forefoot Stabilizer Element and lateral view of Anterior Forefoot Stabilizer Element, (**b**) CFO with first metatarsal head fenestration, (**c**) SAGURO neoprene minimalist shoe.

The second orthosis, called cut-out CFO, was 3D-printed using Hewlett Packard multijet fusion (HP Inc. Palo Alto, CA, USA). The footprint taken for the AFSE was digitized with a Structure Sensor (Occipital Inc., Boulder, CO, USA) using acquisition software developed by TechMed3D, Lévis, QC, Canada (v.2), equipped with 3 cameras, an on-board IMU, and a NU3000 processor. It measures 109 mm long × 18 mm high × 24 mm wide with a depth resolution of 1280 × 960 and the 3DsizeMe app. The design of the orthoses was made using Rhino 3D and Rhino 6 (v.6). The design included a full contact medial arch and a cut-out at the first metatarsal head (Figure 1b), as well as a 1 mm EVA extension under the hallux. The Orthoses was manufactured using a variety of materials, polyamide 12 (PA 12) was used for the shell, and a combination of 30 shore A and 148 kg/cm^3 density polyethylene–ethylene–vinyl–alcohol (PE-EVA) was used for the stabilizing forefoot element and top cover.

2.4. Procedure

Gait analyses of all the recruited individuals were performed in a private Laboratory for Clinical Movement Analysis using the Podoprint® plantar pressure platform (Namrol Group, Barcelona, Spain) [35] with a 1600 sensor with a size of 10 × 10 mm and a pressure range per sensor from 0.4 N/m^2 to 100 N/m^2. The platform was positioned in the center of a room with a 7 meter-long walkway, following the methodology of previous studies [35]. Data were sampled at 100 Hz.

The SAGURO neoprene shoe (China), a minimalist shoe (Figure 1c) that allows the fitting of different FO and which is assumed to have limited mechanical impact on foot function, was used for all the participants [36].

Dynamic plantar pressures were measured with individuals walking at a self-selected speed and the three-step protocol was used [35]. Each patient was positioned at such a distance from the platform, with the third step coinciding right in the center of the pressure platform. Ten 'representative' walking trials were recorded. A trial was considered representative if the participants made clear contact with the pressure platform with good inter-trial consistency, judged by visual inspection by an experienced researcher.

2.5. Data Processing and Analysis

A semi-automatic mapping (SATM) of the obtained pedobarographic fields was conducted using the podoprint Namrol software (Namrol Group, Barcelona, Spain) [35]. The SATM consisted of determining 8 regions of interest (ROI): the hallux (T1) the second toe

(T2), lesser toes (T3–T5), the individual metatarsal heads (MTH) one and two (M1, M2), lesser MTH (M3-M5), the midfoot (MF), and the heel (H) [19]. To achieve this, SATM and manual circumscription of the ROI were performed using the graphical tools of the software. The manual interventions related to the latter are briefly outlined. First, the area corresponding to the 1st MTH was isolated, followed by the area corresponding to the second metatarsal and the lesser metatarsals. Next, the hallux region was isolated, followed by the second toe and the lesser toes. Finally, the area corresponding to the midfoot and the heel area was isolated (Figure 2). The outcome measure associated with these eight ROI was maximum pressure (g/cm^2).

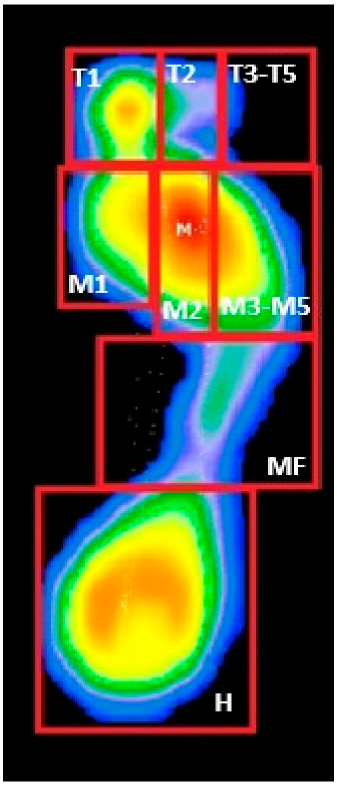


Figure 2. The eight regions of interest. Each red square corresponds to one of the following regions. T1 = hallux, T2 = second toe T3–T5 = lesser toes, M1 = first metatarsal head, M2 = second metatarsal head, M3–M5 = lesser metatarsal heads, MF = midfoot, and H = heel.

Also, the peak pressure ratios between hallux and the 1st MTH, the first and second MTH, and between the first and lesser MTH was calculated.

A second part of the data processing consisted of exporting the Centre of Pressure (CoP) data from all the collected pedobarographic trials [37]. First, all the images of each sample were automatically aligned using the Podoprint Namrol software (v.1) [35]. In this way, the corresponding data for the deviation (both mediolateral and anteroposterior) of each participant were manually exported and inserted into an Excel spreadsheet.

Subsequently, a common coordinate system and origin was established for all the participants. To do that, a first sample was taken as a reference. The data were plotted, and the lowest point in the first phase of the gait cycle (heel contact phase) was set as the initial point, considering it as the origin of the coordinate system. The initial point was not considered due to the potential influences from other factors such as heel fat, tissue compression capacity, etc. Therefore, it is assumed that at this moment, the heel is in complete contact with the ground, marking the beginning of the stance phase. All the remaining CoP exports were adjusted and matched at their lowest point to the trial, so that they started at the same common point, enabling comparison between them and defining our coordinate system accordingly. This same initial point was used as a reference for anteroposterior deviations. The same process was repeated with each of the participants. All the data were subsequently normalized in real time (100% stance phase), using MATLAB 2021a (The Mathworks, Natick, MA, USA).

2.6. Sample Size

The required sample size for the three conditions was determined with a 95% confidence interval and 80% power. This power level provides a high likelihood of identifying a significant difference if one exists. The effect size was calculated based on the smallest observed variation between the condition means, using the combined standard deviation. The analysis determined that 24 participants per group are necessary to achieve the study's goals with the defined confidence and power levels.

2.7. Statistical Analysis

Regarding the 0-D data associated to the eight ROI, a one-way repeated measured analysis of variance (ANOVA) was used to assess for potential differences between the 3 conditions. To assess the differences between the groups in the case of a significant one-way ANOVA test, a post hoc paired *t*-test analysis was performed. Differences were defined as statistically significant at $p < 0.05$. The measure of the effect size was determined by calculating the partial eta squared.

The potential differences between the CoP profiles associated to the three different conditions were assessed by applying 1D SPM repeated measure ANOVA over the normalized time series. If statistical differences were present, post hoc *t*-tests (SPM{t}) were used to determine between-condition differences [38]. All SPM1D analyses were implemented using the open-source SPM1D code (v.M0.1, www.spm1d.org accessed on 11 January 2022) in MATLAB (R2021a, 8.3.0.532, The MathWorks Inc, Natick, MA, USA).

To have a functional interpretation of the 1D data, the following terminology was adopted: (1) loading response (0–19%), midstance (19 to 50%), terminal stance (50–83%) and pre-swing (83–100%) [39].

3. Results

The demographic data of all the participants are shown in Table 1.

Table 1. Demographic characteristics of all participants.

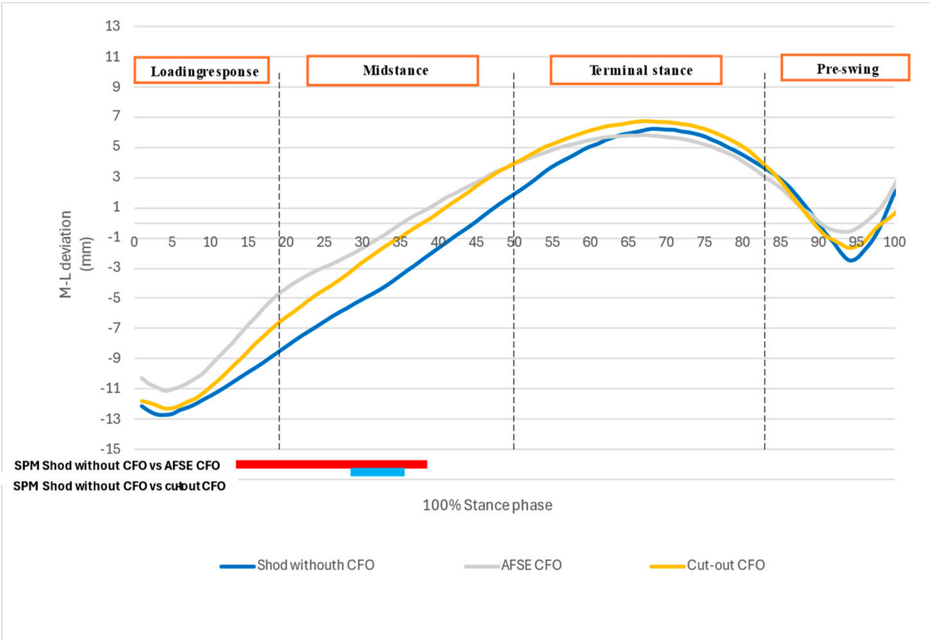
Demographic Characteristics	Mean and SD
Participants	24
Age (years)	34.4 ± 8
BMI (kg/m^2)	23.8 ± 2.7
Size shoe	40.5 ± 2.2
Foot posture index	7.6 ± 1.2
Degrees of dorsiflexion (°)	42 ± 7.7

SD (Standard deviation); BMI (Body mass index); kg/m^2 (kilograms per meter squared); ° (Degrees).

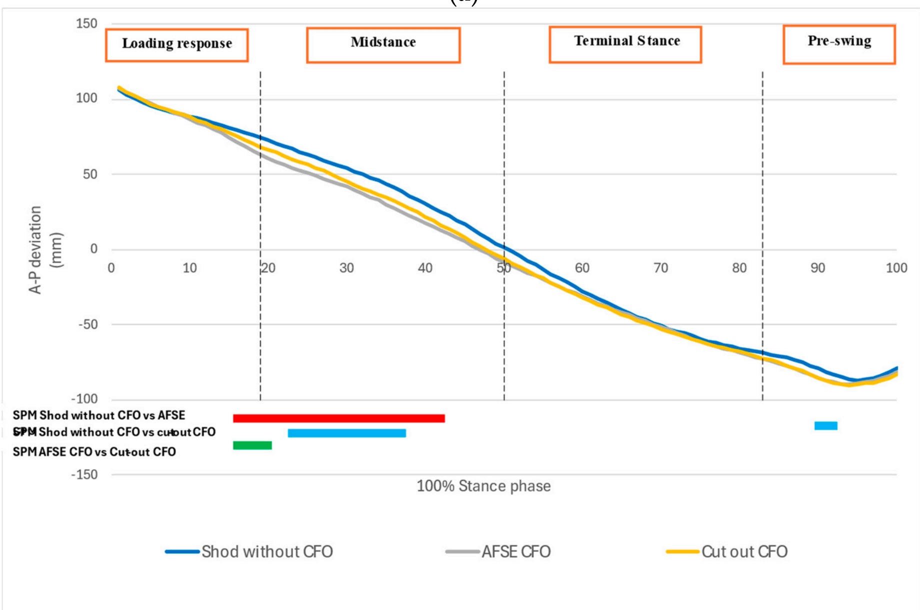
3.1. CoP Data

A graphical synthesis of the average CoP waveforms for each condition is presented in Figure 3a,b.

A significant difference can be observed in the areas where the graphs corresponding to each of the conditions appear further apart, since this implies an increase in the displacement of the COP. In the case, for example, of anterior–posterior displacement, an increase in the distance between the conditions in the midstance phase and the pre-swing phase can be observed, showing a significant difference in the statistical analysis in this part. Depending on whether it is in positive or negative numerical ranges, the displacement will be anterior or posterior, or medial or lateral.



(**a**)



(**b**)

Figure 3. Graphical synthesis of the average COP deviation waveform during 100% of the stance phase. (**a**) Mediolateral (M-L) deviation waveform, (**b**) anteroposterior (A-P) deviation waveform.

Concerning the medio-lateral displacement of the CoP, 1D SPM repeated measure ANOVA analysis revealed significant differences during the loading response and midstance phase ($p < 0.001$) (Table 2). A post hoc t-test indicated that both the CFO conditions were associated with a more medially oriented CoP during midstance ($p < 0.001$ with AFSE CFO and $p = 0.0036$ with cut-out CFO). This difference can be observed in the graphical synthesis as well (Figure 3).

Table 2. Statistical analysis of mediolateral and anteroposterior displacement between 3 conditions.

		Critical Threshold (t)	Supra-Threshold Probability Value (*p*)	Percentage of the Stance Phase (%)
Mediolateral Displacement	Barefoot vs. AFSE	3.127	$p < 0.001$	14–38
	Barefoot vs. Cut-out	3.136	$p = 0.036$	29–35
	AFSE vs. Cut-out	3.228	$p > 0.05$	-
Anteroposterior Displacement	Barefoot vs. AFSE	3.339	$p < 0.001$	16–42
	Barefoot vs. Cut-out	3.368	$p < 0.001$	23–37
	Barefoot vs. Cut-out	3.368	$p < 0.001$	90–92
	AFSE vs. Cut-out	3.420	$p = 0.018$	16–20

With respect to the antero-posterior displacement of the CoP, a 1D SPM repeated measure ANOVA analysis revealed significant differences during the midstance and pre-swing phase (Table 2).

The table shows which percentage of the stance phase this difference occurs in.

A post hoc *t*-test indicated that the AFSE CFO was associated with a more anteriorly located CoP during midstance compared to the shod without a CFO condition ($p < 0.001$).

The post hoc *t*-test further highlighted that the cut-out CFO was associated with a more anterior-located CoP during midstance ($p < 0.001$) and during the pre-swing phase ($p = 0.046$) compared to the shod without a CFO condition.

When considering both the orthotic conditions, post hoc analysis revealed that the AFSE CFO was associated with a more anteriorly located CoP during the loading response and midstance phase ($p = 0.018$) when compared to the cut-out CFO.

3.2. Maximum Pressure Data

Significant differences were found in all the regions of interest, except for the lesser toes and the first MTH (Table 3).

Table 3. Plantar pressure variable associated with the eight regions of interest and maximum pressure ratio (mean and 95% interval confidence).

	Maximum Pressure (Kg/cm^2)				
	Barefoot (1)	**AFSE (2)**	**Cut-out (3)**	***p*Value**	**η^2**
Hallux	1.98 [1.81–2.16] *3	1.99 [1.78–2.19] *3	1.69 [1.55–1.82] *2	0.000	0.346
Second toe	0.71 [0.57–0.85] *2	0.96 [0.76–1.15] *1.3	0.72 [0.62–0.81] *2	0.002	0.276
Lesser toes	0.33 [1.89–0.47]	0.36 [0.22–0.50]	0.39 [0.27-0.51]	0.731	0.010
MTH 1	2.22 [2.07-2.37]	2.28 [2.13–2.43]	2.25 [2.10-2.39]	0.703	0.014
MTH 2	2.69 [2.48-2.90] *3	2.64 [2.44-2.83] *3	2.38 [2.21-2.54] *1.2	0.000	0.349
Lesser MTHs	2.21 [2.06-2.36] *2.3	2.34 [2.21–2.48] *1.3	2.03 [1.90–2.16] *1.2	0.000	0.600
Midfoot	1.49 [1.28–1.69] *2.3	1.75 [1.51–1.99] *1	1.94 [1.63-2.25] *1	0.001	0.491
Rearfoot	2.18 [2.05-2.31] *2.3	2.59 [2.38–2.80] *1.3	2.85 [2.56-3.13] *1.2	0.000	0.484
	Maximum Pressure Ratio				
	Barefoot (1)	**AFSE (2)**	**Cut-out (3)**	***p*Value**	**η^2**
Hallux/ First MTPH	0.96 [0.85–1.07] *2.3	0.9 [0.8–1.0] *1.3	0.8 [0.71–0.88] *1.2	0.002	0.279
First MTPH/Second MTPH	0.83 [0.77–0.9] *3	0.87 [0.82–0.92] *3	1 [0.91–1.02] *1.2	0.001	0.333
First MTPH/Lesser MTPHs	1.00 [0.93–1.09] *3	1 [0.91–1.04] *3	1.15 [1.06–1.23] *1.2	0.000	0.291

* Each of the asterisks and numbers in the table represent the conditions between which the difference is observed.

The post hoc comparison between the AFSE CFO and the shod without CFO condition revealed an increased pressure in the second toe ($p = 0.002$), lesser MTH ($p < 0.001$), midfoot ($p = 0.001$) and rearfoot ($p < 0.001$) with AFSE CFO.

The cut-out CFO resulted in a decreased pressure in the second MTH and lesser toe region ($p < 0.001$) as well as increased pressure in the midfoot ($p = 0.001$) and heel ($p < 0.001$) when compared to the shod without a CFO condition.

Finally, when comparing both orthoses, it was observed that the cut-out CFO resulted in a lower pressure in the hallux, second toe, second MTH, and lesser MTH, as well as an increase in the pressure in the heel.

3.3. Ratios

Significant differences in ratios were found between the three conditions (Table 3).

The AFSE CFO ($p = 0.050$) and the cut-out CFO ($p = 0.033$) were characterized by a lower ratio between hallux and first MTH when compared to the shod without a CFO condition. In addition, a decrease in the ratio is observed with the cut-out CFO compared to AFSE CFO ($p = 0.033$).

Significantly, an increase in the ratio between the first MTH and the second MTH, as well as between the first MTH and the lesser toes, is observed with the cut-out CFO compared to the AFSE CFO and the shod without CFO ($p = 0.004$), ($p = 0.033$).

4. Discussion

The results of our study show a medial and anterior displacement of the CoP, and a redistribution of plantar pressure in the evaluated areas under both study conditions. These observations were collected using minimalist footwear which allows the intrinsic evaluation of the different CFO features. This approach effectively eliminates external factors such as footwear-related variables.

Firstly, we studied the medio-lateral and antero-posterior displacement of the CoP. The result is similar for both treatments. Regarding medio-lateral displacement, both conditions caused a medial shift of the CoP compared to the shod without CFO during midstance, with no significant differences between the two treatments. The primary cause of this shift originates from the full-contact orthotic that shifts the pressure towards the medial arch. This approach is valuable since it helps to address the lateral shift in pressure that has been reported in the literature in patients with HL because of the limited dorsiflexion at the hallux [40].

Regarding the antero-posterior displacement, both treatments exhibit an increase in anterior displacement during midstance; however, cut-out CFO also showed this in the propulsion phase. Some authors [41] demonstrated that patients with HL demonstrated an extended duration of the midstance phase with a reduction in the walking speed and step length. Rambarran et al. [25], showed that using a cut-out CFO in patients with HL led to an acceleration in the anterior displacement speed of the CoP. Therefore, it is conceivable that using a treatment that increases both the anterior displacement of the CoP and its velocity, favoring the propulsive phase, could be beneficial in controlling and avoiding compensations in other joints of the body (typical of HL), preventing overload and the symptoms associated with this condition.

To gain a deeper understanding of why this medial and anterior displacement of CoP occurs and to comprehend more specifically the foot's behavior with different treatments, a subsampling of the pedobarographic data was performed.

With the cut-out CFO, pressure on the hallux and lesser toes significantly decreased while midfoot and heel pressure increased. From this, it can be understood that cut-out CFO improves first MTPJ functionality by reducing pressure in areas typically affected by HL, countering its effect. Although an increase in pressure on the first MTH would be expected, this was not observed in our study.

The literature on plantar pressure distribution with cut-out CFO is limited, with diverse protocols and insole designs yielding heterogeneous results. Gombau et al. [16] reported increased pressure on the first MTH with cut-out CFO, but their population are patients with HL and pronated foot who are in treatment; they applied corrections like the medial heel skive, complicating the isolation of forefoot element effects [30]. Additionally, the use of a cushioning element (Poron) and the absence of EVA extension in the hallux could impact results [26,42]. Menz et al. [26] faced similar challenges than ours in the lesser toes and midfoot, indicating an increase in pressure, but a decrease in the first MTH and heel, contrasting our findings. Their focus on studying patients with painful HL may explain their results, as pain triggers compensatory mechanisms, leading to lateral load transfer. Notably, both studies used rigid thick-soled shoes [16] or the patient's footwear [26]; this could lead to an important bias, due to the change in the characteristics of each of the patients' shoes, being always more convenient to use the same type of shoe for all the subjects.

A study similar to ours in terms of FO design [26], showed the same results as our study, but further investigation is needed to determine if the hallux pressure reduction is due to improved functionality or the use of slightly softer materials. In addition to the study of plantar pressure, to provide a more functional perspective, measurements of the ratios were conducted [18].

AFSE CFO demonstrates distinct pressure patterns with increased pressure on the second toe, lesser toes, midfoot, and heel. Like cut-out CFO, there is a reduction in the ratio between the hallux and the first MTH, indicating a medial load shift. The CoP analysis revealed a more anterior displacement in load response and midstance, suggesting that AFSE CFO may play a role in propulsion, crucial for HL patients. Despite these observations, the lack of prior research complicates finding comparisons highlighting the necessity for further investigation to draw definitive conclusions.

The observed biomechanical changes could have a significant impact on both symptomatology and gait efficiency in patients with HL. Firstly, the medial displacement of the CoP, present in both the treatment conditions, could reduce the lateral compensatory shift often seen in these patients due to limited dorsiflexion of the first MTPJ. This would decrease lateral load, thereby reducing pain and complications in other areas of the body that typically arise from compensatory mechanisms. Additionally, the anterior displacement of the CoP during the propulsion phase suggests an improvement in push-off efficiency during walking. This could restore a more natural transition from midstance to propulsion, optimizing step efficiency and improving gait mechanics in HL patients, who often exhibit a prolonged midstance phase and reduced walking speed. Moreover, the reduction in pressure on the hallux and its redistribution towards the midfoot and heel with the cut-out CFO could indicate improved functionality of the first MTPJ, alleviating pressure in the areas typically affected by HL and thus reducing overload-induced pain in these regions. Future studies should further investigate the foot biomechanics under these same conditions. Therefore, these findings not only point to symptom relief for HL, but also suggest improvements in gait efficiency, which could help prevent future injuries and compensatory mechanisms in other joints.

This highlights the clinical importance of the evaluated treatments. In both cases, future studies should investigate the biomechanical effects produced by both elements to establish a clear conclusion regarding the behavior of this anatomical segment during walking.

Limitations

Despite offering valuable insights, our study has methodological limitations. The relatively modest sample size emphasized the need for replication with a larger and more diverse group. We only assessed the direct effect of the CFO, and the impact of prolonged exposure remains unclear. Furthermore, the use of an in-shoe pressure system could offer better quantification of orthotic-induced load redistribution. In studying SHL, the inclusion of patients with a pronated FPI suggests implicit FHL, highlighting a factor for consideration. Furthermore, our focus on the short-term effects of orthotic intervention omits the consideration of the patient adaptation period. Furthermore, it remains unclear what the efficacy would be in a longer term.

5. Conclusions

Cut-out CFO causes alterations in the medial and anterior pattern of the CoP, brought about by a decrease in pressure on the lateral area of the foot and the hallux, along with a transfer of loads to the first MTH. AFSE CFO cause a medial and an anterior shift of the CoP due to an increase in loads on first MTH.

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