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The clinical and biomechanical effects of customized foot orthoses in individuals with plantar heel pain: A pre-post intervention study☆

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ABSTRACT

Background: Customized foot orthoses (CFOs) are often recommended for the management of plantar heel pain. However, there is a lack of information regarding lower limb and multi-segment foot motion during gait.

Research question: This study aimed to determine the effects of heat moulded CFOs on foot and lower limb kinematics when compared with prefabricated foot orthoses (PFOs) and wearing no orthoses (shod condition), and to determine the short-term effects of CFOs on pain intensity and foot function.

Methods: The immediate effects of CFOs on the lower limb and multi-segment foot motion were assessed. Participants were then asked to use the CFOs for one month and foot pain, function, and temporal-spatial parameters were assessed at baseline and at one month follow up.

Results: Thirty-five participants (22 females), aged 40.1 (10.5) years, with a mean duration of symptoms of 12.59 months were recruited. The symptomatic limbs showed a higher forefoot varus angle and greater rearfoot and forefoot corrections were required compared to the non-symptomatic limbs. When compared with PFOs and shod conditions, CFOs provided the least forefoot and knee motion in the transverse plane during contact phase ($P < 0.05$, d=0.844–1.720), least rearfoot motion in the coronal plane during midstance ($P < 0.05$, d=0.652), and least forefoot motion in the frontal plane, knee motion in the transverse plane, and hallux motion during the propulsive phase ($P < 0.05$, d=0.921–1.513). Significant improvements were seen for foot pain and function ($P < 0.05$, d=1.390–2.231) with significant increases in cadence and walking velocity after one month of CFO use ($P < 0.05$, d=0.315–0.353), and those most likely to respond had greater pain and less ankle eversion ($P < 0.05$, d=0.855–1.115).

Significance: CFOs appear to improve pathological biomechanics associated with plantar heel pain. After one month follow up, the CFOs decreased pain intensity and increased foot function, and showed significant improvements in temporal and spatial parameters of gait.

1. Introduction

Plantar heel pain (PHP) is the most common foot condition diagnosed by podiatrists, with more than 1 million people estimated to seek professional care each year [1]. A common physical treatment for PHP used in clinical practice is the use of foot orthoses which are widely recommended [1,2]. The mechanisms of foot orthosis have been reported to include reductions in plantar fascia strain during stance phase by lifting the medial longitudinal arch and decreasing abnormal foot pronation [3], with foot orthoses being purported to maintain the height of the medial longitudinal arch and reduce the tensile strain in the plantar fascia [3,4].

As described in the contemporary guidance published in 2021, there is strong evidence to suggest that customized foot orthoses (CFOs)

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provide short-term pain reduction [5]. To date a number of studies have used subjective assessments to investigate the effectiveness of CFOs for the treatment of PHP [6–12], however the biomechanical effects during gait are unclear with only two studies including gait analysis evaluating the use of CFOs in people with PHP [13,14]. Since the presence of PHP has been described as excessive foot kinematics during gait [15], which could induce adverse knee and hip motions in the transverse plane through the coupling mechanism of the foot, tibia, and femur [16]. A previous study found that alterations of lower-extremity movement patterns, including excessive medial rotation of the femur and tibia, increased the risk of PHP [17]. In addition, significant differences in the forefoot, rearfoot, knee and hip motion during each subphase of the stance gait have been reported between individuals with PHP and controls [18]. A number of studies support the use of foot orthoses to reduce knee motion in the transverse plane and rearfoot motion in the frontal plane, and have reported a reduction of excessive foot kinematics during gait in individuals with lower-extremity injuries [19,20]. To the authors' knowledge no studies have evaluated the effectiveness of foot orthoses alongside lower limb and multi-segment foot kinematics and ground reaction forces during gait in individuals with PHP. Therefore, the objectives of this study were to determine the immediate effects of CFOs on the lower limb and multi-segment foot kinematics and ground reaction forces when compared with PFOs and shod conditions during the stance phase of walking, and to determine the short-term effects of CFOs on foot pain and function and gait parameters in individuals with PHP.

2. Methods

A within-subject cross-over design was used to explore the effects of foot orthoses under three randomized conditions; walking with shoes, shoes with a PFO, and shoes with a CFO. Participants were additionally asked to use the CFOs for one month.

The sample size was calculated using G*power software version 3.1.9.4. At least 27 participants were required to detect differences in the kinematics between the three conditions with a power of 80 %, a significance level of 5 % and a medium effect size (Cohen's d=0.5). PHP was diagnosed by a physical therapist using the following criteria: pain in the proximal attachment of the plantar fascia on the medial tubercle of the calcaneus, sharp or deep dull pain, first-step pain which recedes after a few steps, pain after prolong walking or standing, and pain during barefoot walking or going upstairs [1].

Inclusion criteria were; aged 18–60 years old meeting the diagnostic criteria of PHP with symptoms lasting at least 6 weeks [21], and an average pain intensity during the last week of at least 30 mm on a 100 mm visual analog scale (VAS). Exclusion criteria were: BMI > 30 kg/m^2, a leg length difference of more than 1 cm, a positive sciatica test, history of lower extremity fracture, or diagnosed with at least one of the following; gout, diabetic neuropathy, rheumatoid arthritis, systemic lupus erythematosus, cancer, infection disease or tumour. All participants provided written informed consent prior to data collection, and the research protocol was approved by the center of Ethical Reinforcement for Human Research of Mahidol University (COA No.MU-CIRB 2020/178.0511).

2.1. Foot orthoses

Participants were provided with one pair of three-quarter length PFOs and CFOs by a physical therapist who had 7 years' experience of treating musculoskeletal problems using foot orthoses. The PFOs were made from a firm density polyethylene foam with a medial arch support and a gel heel cup (Sofsole Plantar fascia insole) and were sized according to foot length (Fig. 1A). The CFOs (Fig. 1B) included a medial-arch support made from thermoplastic material (Fig. 1C), with a corrective medial wedge of 3 mm using soft foam along the full length of the orthosis (Fig. 1D). The medial-arch support had a top leather layer of 1.2 mm and two layers of 1 mm polyvinyl chloride (PVC), which were

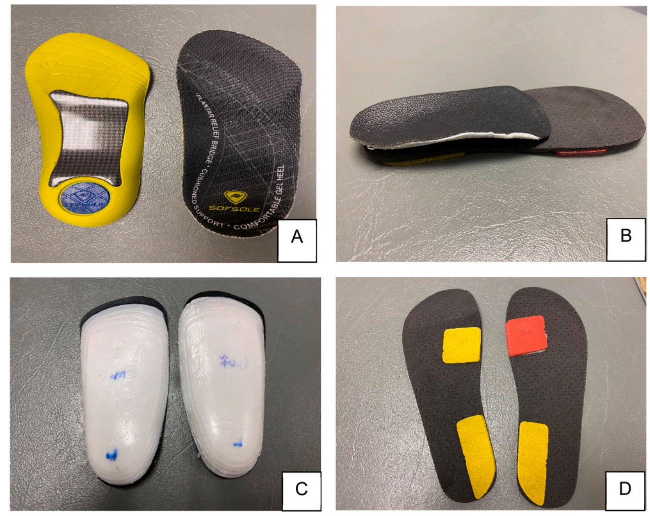

Fig. 1. Customized foot orthoses in the present study (A: PFO, B: completed CFO, C: inferior view of medial arch support, D: medial wedge).

heat moulded to fit the individuals foot shape whilst seated. An assessment of the forefoot angle was used to determine the amount of orthotic correction required [22], with a 50 % correction of the forefoot angle for the rearfoot varus wedge to a maximum of 6 degrees, and the forefoot varus wedge posted at approximately 60 % of the forefoot angle to a maximum of 8 degrees [23,24].

2.2. Assessment of immediate effects

Physical characteristics were assessed including; femoral anteversion, tibial torsion, ankle inversion/eversion, foot posture, and rearfoot and forefoot angle. A 10 camera three-dimensional motion analysis system (Vicon, V5 series, Oxford, UK) was used to track the lower limb and multi-segment foot kinematics during gait at 100 Hz over an 8-m walkway, which were synchronized with two force plates (AMTI, model OR6–7, USA), which collected data at 1000 Hz. Forty-two retro-reflective markers were applied on the shoe surface following the Plug-In-Gait (PIG) model and Oxford Foot Model (OFM) by the same physical therapist (Supplementary Figure). Participants were asked to walk under three conditions in a randomized order; shoes, shoes with PFO, and shoes with CFO, to determine the immediate effects of the orthoses, using standardised commercially available athletic shoes (Adidas, Model: Duramo SL). A metronome was used to control the self-selected cadence from heel contact of one foot to another. Before data collection in each condition, participants were asked to walk for approximately one minute to habituate to the testing condition at the same cadence. Data were collected for 3–5 successful gait trials per condition. The comfort level of each condition was assessed after walking using a 0–10 numerical rating scale, with higher scores representing greater comfort.

2.3. Data processing

Marker data were tracked using Nexus (version 2.8.1), and the kinematic and kinetic data were filtered using a 4th order zero-lag, low-pass Butterworth filter with cut-off frequencies of 6 Hz and 30 Hz, respectively. Initial contact and toe-off events for each foot were identified using the vertical ground reaction force (GRF) using a 10 N threshold. The motion of the pelvis, hip, knee, rearfoot (hindfoot relative to tibia), forefoot (forefoot relative to hindfoot), and hallux were recorded for the stance phase of each foot and normalized to 100 points. Range of motion was recorded for the contact phase, midstance phase, and propulsive phase [25]. In addition, anteroposterior, mediolateral, and vertical GRFs were recorded.

2.4. Assessment of effects after one month

The foot function index (FFI) [26] and VAS [27] were used to collect foot pain and function at baseline and one month follow up, which were considered alongside previous reported minimal clinical important differences (MCID), with a MCID of 9 mm for VAS and MCID of 6.5 points for FFI [28]. The CFOs were used within participants normal footwear during weight-bearing activities as much as possible, or for at least 6 h per day maintaining their usual routine activities. Participants with an increase in FFI of more than 6.5 points were categorized into a responder group; while the remainder were categorized into a non-responder group. The cut off value of 6.5 points was derived from the mean change of FFI score in 34 participants who reported 'no change' versus 181 who reported some change [28]. In addition, a 3 m Zebris force platform (Zebris FDM, Isny, Germany) was used to collect temporal and spatial gait parameters at a self-selected speed during barefoot walking for 3 trials at a sampling rate of 100 Hz at baseline and one month follow up. Cadence, walking velocity, stride time, stride length, step time, step length, step width, percentage stance time, percentage single support time, and percentage double support time were recorded.

2.5. Statistical analysis

Shapiro-Wilk tests were used to determine if the data were normally distributed. For normally distributed data descriptive statistics were reported from the symptomatic limb. Repeated Measures ANOVA (RM ANOVA) tests were used to compare the immediate effects on the kinematic and kinetic data between the three conditions. Post-hoc pairwise comparisons with a Bonferroni correction were used to further explore the differences between the conditions when a main effect was seen. For non-normally distributed data Friedman tests and Wilcoxon signed-rank tests were used.

When considering the effects of using the CFOs for one month either paired samples t-tests or Wilcoxon signed-rank tests were used to determine changes in pain intensity, foot function, and gait parameters. In addition, either independent samples t-tests or Mann-Whitney U tests were used to compare the baseline characteristics between the responder and non-responder groups. All statistical analyses were performed using SPSS software version 22.0 (IBM Statistics, USA), with an alpha level set at < 0.05. Effect sizes using Cohen's d were calculated for all variables [29].

3. Results

Thirty-five individuals with PHP (26 females) were recruited. Participant characteristics were; aged 40.1 years (SD=10.5), body mass index (BMI) 26.3 kg/m^2 (SD=5.6), and 12.6 months (SD=12.8) duration of symptoms. The physical characteristics showed that the symptomatic limbs had a higher forefoot varus angle than previously reported normative values [23,24,30], and greater rearfoot and forefoot corrections were required on the involved sides compared to the uninvolved sides (Table 1).

The RM ANOVA showed significant main effects between the three conditions on forefoot, rearfoot, hallux, and knee motions. When compared with PFOs and shod, the CFOs provided the least forefoot and knee motions in the transverse plane ($P < 0.001$ and $P = 0.002$) respectively, with large effect sizes seen during the contact phase, least rearfoot motion in the coronal plane ($P = 0.019$) with medium effect size during the midstance phase, and least forefoot motion in the frontal plane, knee motion in the transverse plane, and hallux motion ($P = 0.002$, $P = 0.033$, $P = 0.004$) respectively, with large effect sizes during the propulsive phase (Table 2, Fig. 2).

When considering one month follow up data two participants were lost; one felt the CFOs were uncomfortable and the other had symptoms of Covid-19 and was self-isolating. After one month of CFO use, there were significant improvements in morning pain, worst pain, and average pain over the previous week ($P < 0.001$), and FFI scores were higher in all subscales ($P < 0.001$). In addition, significant decreases in stance time, double support time, and stride time were seen at one month compared to baseline ($P = 0.011$, $P = 0.004$. $P = 0.028$), with greater cadence and walking velocity ($P = 0.036$, $P = 0.013$), respectively (Table 3). Participants also felt more comfortable when wearing the CFOs compared with both PFOs and shoes only (see Supplementary table). Using the FFI threshold of 6.5 points seven of the participants were categorized as non-responders and 26 were categorized as responders, with the responders showing significantly lower ankle eversion angles ($P = 0.041$), worse morning pain intensity ($P = 0.009$), and worst pain intensity ($P = 0.016$) than the non-responders (Table 4).

Table 1
Participant characteristics (n = 35). Data are shown as mean (SD) or number (%).

Characteristics	Mean (SD) / number (%)
Age, years	40.1 (10.5)
BMI, kg/m^2	26.3 (5.6)
Females, number (%)	22 (62.86)
Duration of PF symptoms, months	12.59 (12.80)
Femoral anteversion angle, degrees	14.63 (2.79)
Tibial torsion angle, degrees	22.48 (4.09)
Ankle inversion angle, degrees	14.60 (5.91)
Ankle eversion angle, degrees	6.26 (2.70)
Rearfoot angle, degrees	5.14 (3.00)
Forefoot angle, degrees	17.69 (7.57)
Foot posture index (FPI), scores	3.81 (4.79)
Rearfoot varus wedge	
Involved side, degrees	4.64 (1.78)
Uninvolved side, degrees	3.89 (1.64)
Forefoot varus wedge	
Involved side, degrees	5.31 (1.81)
Uninvolved side, degrees	4.86 (2.32)
Comfort with foot orthoses (FOs)	
Shoe, points	5.62 (2.01)
Prefabricated FOs, points	6.34 (2.05)
Custom FOs, points	7.28 (1.63)

4. Discussion

The objectives of this study were to determine the immediate effects of CFOs on the lower limb and foot kinematics and ground reaction forces when compared to PFOs and shoes only, and to determine the short-term effects over one month of wearing CFOs on pain intensity, foot function and temporal and spatial parameters of gait in individuals with PHP.

During the contact phase, the CFOs produced the least forefoot and knee motion in the transverse plane when compared with PFOs and shod. Normally, the forefoot adducts with inversion of the rearfoot at heel contact, and then immediately abducts with eversion of the rearfoot for weight acceptance, which could increase the relative distance between the calcaneus and metatarsals during early stance phase [31]. The greater relative distance may induce more tensile stress on the plantar fascia [32]. The present findings showed that CFOs provided the least rearfoot motion in the frontal plane during the midstance phase. This indicated that the CFOs with the medial wedge at the forefoot and rearfoot could reduce plantar fascia tension, which might then lead to an increase of forefoot stability during late stance phase.

Biomechanically, the hallux extends and the foot supinates to increase the rigid lever arm via the windlass mechanism during the propulsive phase [33]. Alterations of load distribution under the foot may also affect forefoot instability and the 1st metatarsophalangeal joint dysfunction during propulsion [15], and more extension of the hallux may cause excessive traction forces to the calcaneus, which could be transmitted to the plantar fascia [34]. The findings of this study showed

Table 2
Comparisons of the mean (SD) or median (IQR) of the lower limb and multi-segment foot kinematics and ground reaction force (GRF) among the shod condition, PFO condition, and CFO condition in each subphase of stance gait (n = 35).

	Contact phase					**Midstance phase**					**Propulsive phase**				
	Mean (SD) / Median (IQR)			***P***	**Effect size**	**Mean (SD) / Median (IQR)**			***P***	**Effect size**	**Mean (SD) / Median (IQR)**			***P***	**Effect size**
	Shod	**PFO**	**CFO**			**Shod**	**PFO**	**CFO**			**Shod**	**PFO**	**CFO**		
Pelvis															
Sagittal ()	1.9 (0.8)	1.9 (0.8)	2.0 (0.9)	0.589	0.230	2.8 (1.0)	2.8 (1.2)	2.6 (1.2)	0.358	0.327	2.0 (0.9)	1.9 (0.9)	2.0 (1.0)	0.409	0.307
Coronal ()	3.8 (1.3)	3.6 (1.4)	3.9 (1.2)	0.131	0.464	6.0 (2.0)	5.8 (2.0)	5.8 (2.0)	0.340	0.333	4.0 (1.0)	3.8 (1.1)	4.0 (1.0)	0.288	0.364
Transverse ()	2.4 (1.3)	2.5 (1.4)	2.4 (1.4)	0.681	0.201	7.8 (2.1)	7.4 (2.7)	7.5 (2.1)	0.627	0.230	2.3 (1.3)	2.3 (1.3)	2.2 (1.3)	0.885	0.110
Hip															
Sagittal ()	12.4 (3.1)	12.8 (2.7)	12.7 (2.8)	0.505	0.263	28.8 (4.2)	28.6 (4.2)	28.3 (4.6)	0.471	0.278	8.7 (2.5)	8.5 (2.2)	9.0 (2.6)	0.342	0.340
Coronal ()	6.9 (2.3)	6.8 (2.3)	6.7 (2.2)	0.765	0.168	5.4 (1.9)	5.3 (1.9)	5.2 (2.2)	0.491	0.271	10.4 (2.8)	10.3 (2.6)	10.1 (2.9)	0.539	0.247
Transverse ()	26.7 (10.1)	26.5 (9.3)	27.7 (10.9)	0.281	0.352	14.5 (5.7)	13.4 (5.5)	14.1 (5.2)	0.102	0.492	17.6 (9.5)	18.7 (11.1)	19.2 (11.1)	0.148	0.439
Knee															
Sagittal ()	8.9 (3.6)	8.3 (2.9)	8.4 (3.4)	0.135	0.459	8.0 (3.1)	7.4 (2.9)	7.4 (2.7)	0.065	0.561	27.2 [16.5,31.1]	27.1 [17.7,32.3]	25.1 [19.4,33.3]	0.843	0.183
Coronal ()	5.9 (2.4)	5.6 (2.6)	6.1 (2.7)	0.183	0.419	5.0 (2.7)	5.1 (2.8)	5.0 (2.7)	0.826	0.142	22.8 (10.3)	22.0 (9.9)	22.6 (10.3)	0.349	0.327
Transverse ()	16.0 (4.7)	14.4 (4.3)†	13.9 (4.0)‡	0.002**	0.844	8.0 (2.7)	7.7 (2.8)	7.7 (2.9)	0.584	0.238	9.4 [6.0,12.4]	7.3 [4.6,11.9]	7.3 [4.6,9.7]‡,*	0.033**	0.921
HF-TB															
Sagittal ()	16.1 (3.5)	16.9 (3.2)	17.0 (3.2)	0.226	0.408	17.1 (5.1)	18.9 (4.2)†	18.3 (4.4)‡	0.007**	0.728	31.5 (7.0)	33.1 (8.0)	31.8 (7.9)	0.114	0.487
Coronal ()	26.9 (8.2)	25.5 (8.0)	25.4 (8.2)	0.202	0.403	18.6 (7.5)	17.2 (6.8)†	16.9 (6.5)‡	0.019**	0.652	14.4 (11.4)	14.7 (8.4)	15.8 (7.8)	0.343	0.327
Transverse ()	9.9 (3.8)	9.9 (3.8)	9.9 (3.8)	0.992	0.020	7.8 (3.7)	7.5 (3.9)	7.4 (3.2)	0.934	0.090	15.2 (9.2)	15.6 (10.2)	14.7 (9.1)	0.511	0.263
FF-HF															
Sagittal ()	4.9 (1.3)	5.1 (1.6)	4.9 (1.4)	0.495	0.271	2.1 (0.9)	2.3 (1.0)	2.4 (0.8)	0.177	0.459	2.6 [2.0,3.3]	2.4 [2.1,3.4]	2.2 [1.9,3.2]	0.918	0.140
Coronal ()	1.9 [1.6,2.3]	1.6 [1.3,2.2]	1.6 [1.3,2.0]	0.110	0.726	1.6 (0.6)	1.6 (0.6)	1.6 (0.5)	0.762	0.168	1.5 [1.2,2.0]	1.1 [0.9,1.9]†	1.2 [0.8,1.5]‡	0.002**	1.513
Transverse ()	4.0 (1.3)	3.9 (1.2)	2.8 (0.9)‡,*	<0.001**	1.720	1.9 [1.5,2.5]	1.9 [1.5,2.3]	1.9 [1.6,2.1]	0.879	0.183	3.6 (1.6)	3.4 (1.3)	3.5 (1.4)	0.536	0.255
Hallux															
Sagittal ()	4.5 [2.8,6.8]	4.8 [2.8, 6.6]	4.3 [2.1,6.4]	0.209	0.591	5.8 (2.6)	4.9 (2.0)†	5.5 (2.6)*	0.026**	0.696	23.4 [19.3,33.4]	22.8 [14.6,29.5]†	19.4 [16.0,25.5]‡	0.004**	1.272
GRF															
Anterior-posterior (N)	15.7 (4.7)	16.4 (4.2)	16.1 (4.2)	0.603	0.220	-	-	-	-	-	21.2 (3.1)	21.2 (3.1)	20.6 (3.3)	0.192	0.408
Medial-lateral (N)	6.2 (2.7)	5.8 (1.9)	6.0 (2.0)	0.299	0.346	-	-	-	-	-	4.7 [2.8, 6.1]	4.7 [3.3, 5.7]	4.5 [2.8, 5.6]	0.215	0.569
Vertical (N)	109.6 (9.7)	110.5 (10.9)	109.5 (10.0)	0.553	0.238	-	-	-	-	-	105.9 (10.1)	106.3 (10.6)	105.9 (10.0)	0.930	0.090

† Significant difference between shod and PFO. ‡ Significant difference between shod and CFO. * Significant difference between PFO and CFO. ** Significant difference of the main effect

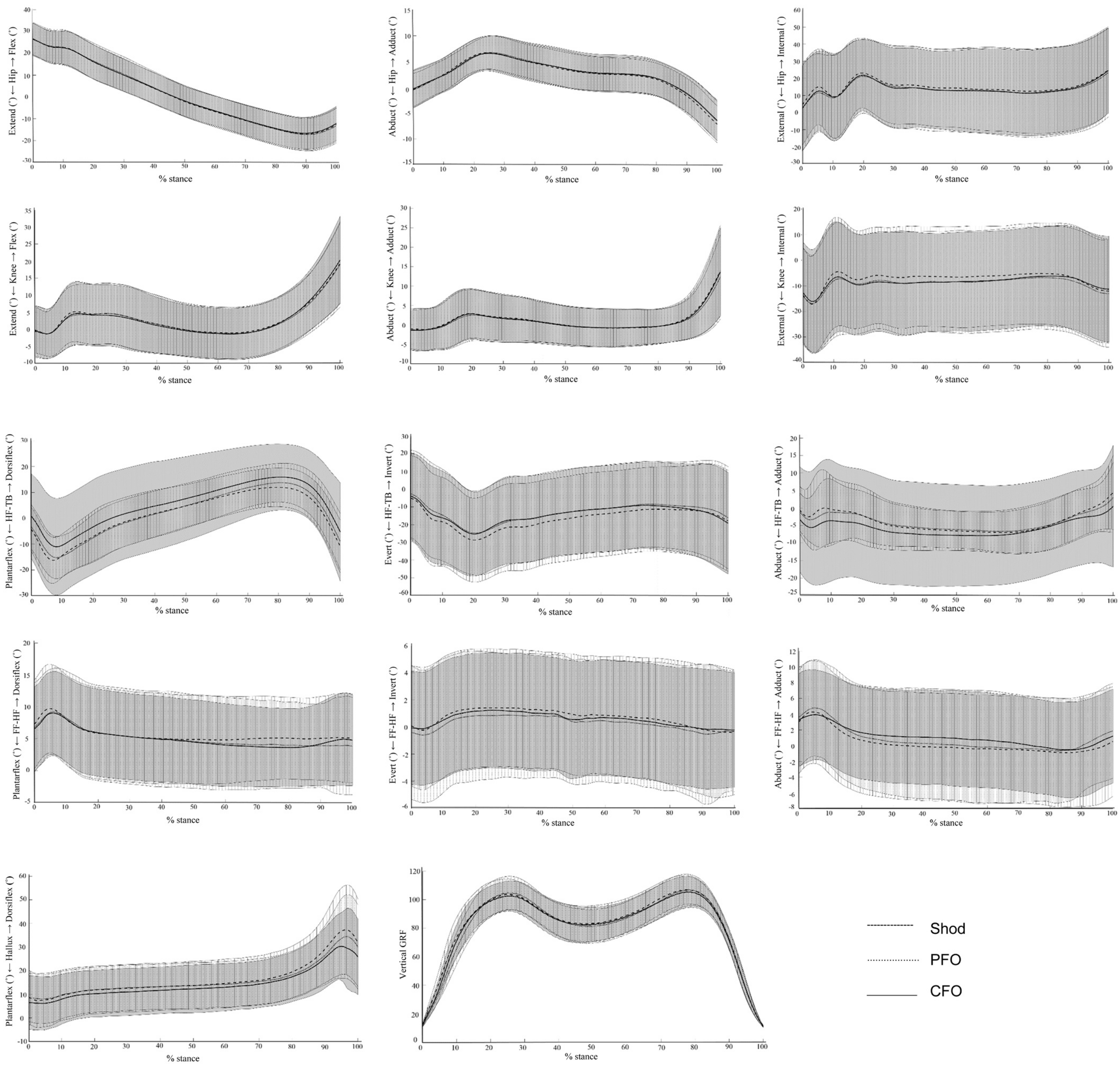

Fig. 2. Comparisons of the lower limb kinematics among the shod condition, PFO condition, and CFO condition in each subphase of stance gait (n = 35) (Shod represented by a dashed line, PFO represented by a dotted line, and CFO represented by a straighted line).

the CFOs provided the least hallux motion during the propulsive phase compared with the other conditions. Forces generated in the plantar fascia from the windlass mechanism might decrease with the use of CFOs.

In addition to changes in foot motion, the CFOs decreased the transverse plane knee motion during the contact and propulsive phases. A previous study found significant differences in transverse plane knee movement between people with PHP and healthy controls [18]. This has been attributed to a coupling mechanism of the foot, tibia, and femur with prolonged internal tibial and femoral rotation from early to mid-stance [16]. Such mechanisms are supported by a delayed external tibial rotation during late stance, which is proposed to increase patella maltracking and excessive tension within the plantar fascia [16,33]. The supination of the foot produces a coupling mechanism inducing external rotation of the tibia through the articulations at the subtalar and mid-tarsal joints [33], with the plantar fascia tension needing to increased to provide foot stability during propulsion [32]. The effects of CFOs in decreasing the transverse plane knee movement could thus provide the foot flexibility and foot stability, with a reduction in plantar fascia tension during early to late stance phase of walking.

After one month of wearing the CFOs, the participants showed significantly less pain intensity and greater foot function than at baseline. There were also increases in cadence and walking velocity, which were in accordance with decreasing stance time, decreasing total double support time, and decreasing stride time. This is in agreement with previous studies investigating the effectiveness of CFOs in people with PHP, which reported significant improvements in pain intensity, foot function, and walking distances after 45 days, 90 days, and 180 days follow up [13], showing significant pain reduction and longer episodes of walking[14].

The present study found that 26 participants who responded to the treatment of CFOs had more morning pain and worst pain intensity than

Table 3
Comparison of the mean (SD) or median (IQR) of the pain intensity, foot function index and gait parameters between pre- and post- 1 month after receiving CFO.

	Baseline (n = 35)	1-month follow up (n = 33)	t score / z score	*P*	Effect size
Pain intensity					
Morning pain, points	7.00 [4.00, 8.12]	4.00 [2.00, 6.00]	-3.698	<0.001*	1.390
Worst pain, points	7.00 [6.00, 8.12]	3.00 [5.00, 7.00]	-4.119	<0.001*	1.647
Average pain, points	5.00 [3.69, 7.00]	3.00 [1.00, 5.00]	-3.426	0.001*	1.452
Foot function index					
Pain subscale, points	58.63 [38.57, 65.71]	31.11 [14.44, 55.56]	-4.746	<0.001*	2.151
Disability subscale, points	52.52 [33.83, 64.44]	21.67 [12.50, 55.56]	-4.521	<0.001*	1.947
Activity limitation subscale, points	24.00 [4.00, 34.50]	9.00 [0.00, 12.00]	-4.826	<0.001*	2.231
Total, %	47.14 [31.80, 58.00]	25.00 [13.59, 44.67]	-4.796	<0.001*	2.201
Gait parameter					
Step length, cm	53.84 (3.72)	54.68 (5.03)	-0.964	0.342	0.187
Step time, sec	0.62 (0.06)	0.60 (0.06)	1.412	0.167	0.246
Stance time, %	66.24 (1.85)	65.48 (1.86)	2.689	0.011*	0.408
Single support time, %	35.04 (1.90)	35.54 (1.81)	-1.653	0.108	0.269
Double support time, %	30.86 (3.41)	29.81 (3.03)	3.054	0.004*	0.319
Stride length, cm	106.50 [104.92, 111.83]	105.00 [109.83, 114.75]	-1.625	0.104	0.554
Stride time, sec	1.27 (0.12)	1.22 (0.10)	2.293	0.028*	0.366
Step width, cm	10.24 [8.48, 12.55]	10.79 [8.52, 12.36]	-1.103	0.270	0.369
Cadence, steps/min	96.00 (9.05)	98.98 (7.65)	-2.190	0.036*	0.353
Velocity, m/s	0.87 (0.10)	0.90 (0.09)	-2.633	0.013*	0.315

* Significant difference between pre- and post- 1 month.

Table 4
Comparison of the mean (SD) or median (IQR) of the participant characteristics at baseline between non-responded (n = 7) and responded (n = 26) groups using the FFI. Those with FFI change more than 6.5 points were in the responded group.

	Non-responded group (n = 7)	Responded group (n = 26)	t score / z score	*P*	Effect size
Age, years	42.63 (14.42)	39.22 (9.87)	0.769	0.448	0.310
BMI, kg/m^2	24.85 (4.54)	26.85 (6.32)	-0.830	0.413	0.334
Duration of PF symptoms, months	12.00 [3.00, 36.00]	6.00 [3.50, 12.00]	-0.749	0.454	0.259
Femoral anteversion angle, degrees	14.88 (3.52)	14.65 (2.50)	0.205	0.839	0.083
Tibial torsion angle, degrees	23.00 (3.70)	21.93 (3.89)	0.693	0.493	0.279
Foot posture index (FPI), scores	1.38 (4.81)	4.44 (4.78)	-1.593	0.121	0.641
Ankle inversion angle, degrees	16.88 (7.28)	14.33 (5.62)	1.051	0.301	0.423
Ankle eversion angle, degrees	8.00 (3.93)	5.78 (2.10)	2.125	0.041*	0.855
Rearfoot angle, degrees	5.00 [4.00, 5.00]	5.00 [2.00, 6.00]	-0.120	0.905	0.041
Forefoot angle, degrees	15.75 (5.12)	17.85 (8.46)	-0.663	0.512	0.267
Morning pain intensity, points	3.94 (3.51)	6.82 (2.28)	-2.769	0.009*	1.115
Worst pain intensity, points	5.50 [4.13, 7.75]	8.00 [7.00, 9.00]	-2.418	0.016*	0.896
Average pain intensity, points	3.70 (3.15)	5.38 (1.81)	-1.773	0.087	0.769
Step length, cm	53.28 (5.11)	54.24 (3.72)	-0.530	0.600	0.241
Step time, sec	0.62 (0.03)	0.62 (0.07)	0.029	0.977	0.013
Stride length, cm	105.17 [95.17, 115.10]	108.00 [105.38, 112.42]	-0.900	0.368	0.328
Stride time, sec	1.23 [1.20, 1.33]	1.23 [1.15, 1.38]	-0.250	0.803	0.090
Step width, cm	10.59 (2.77)	11.20 (3.16)	-0.437	0.665	0.199
Cadence, steps/min	96.04 (6.84)	96.38 (9.70)	-0.081	0.936	0.037
Velocity, m/s	0.88 (0.07)	0.87 (0.10)	0.215	0.831	0.116

* Significant difference between groups.

those that didn't respond. According to the results, average morning pain and worst pain in the non-responder group could be categorized into a moderate pain level, which was identified by the VAS ranging from 3.5 to 7.4. While, the responder group had severe levels of pain (VAS≥7.5) [35], and showed less ankle eversion. Therefore, individuals with more pain and less ankle eversion may have more potential to benefit from the CFOs than those with less pain and higher ankle eversion angles.

To the authors' knowledge this is the first study to determine the effects of foot orthoses on joint kinematics during gait in individuals with PHP. Although only the immediate effects of joint kinematics were investigated, clinical outcomes and temporal and spatial parameters of gait highlighted short-term effects after one month. The CFOs used in this study are a low cost, quick to administer intervention that can provide positive outcomes. However, when considering the production of CFOs, the therapist used a heat moulding method instead of positive moulding using negative casts. The present results thus reflect the biomechanical effects of heat-moulded CFOs and not other methods of CFO production. In addition, the foot assessment using the Root method [22] was used to determine appropriate angles for medial rearfoot and forefoot wedges in CFOs. Although previous studies have reported poor correlation between the clinical rearfoot angle and rearfoot kinematics during stance phase of gait [36,37], and have been shown not to reflect the interaction between the foot and the ground [38]. The assessments following Root [22] are still widely used by podiatrists within clinical practice to determine the rearfoot and forefoot correction angles for medial wedges in CFOs [39–41], with the medial wedges at the rearfoot and forefoot appearing to be effective in controlling excessive foot pronation during stance phase [39].

Some limitations of this study should be noted. The different types of foot orthoses were unblinded from the participants and researchers. The addition of a control group in the one month follow up would help to compare the effects with the CFO group, therefore further randomized controlled trials should be conducted to confirm these findings. The responder analysis was underpowered with unequal samples with 7 participants in the non-responder group and 26 in the responder group, and most of the participants were classified as obese using the Western Pacific regional office standard, which could produce skin movement and associated marker measurement error. The study took a pragmatic view and used shoe mounted markers to study kinematic parameters in individuals with PHP, however, there is evidence both in favour and against this method [42–44], the results and conclusions should be considered with caution.

5. Conclusion

CFOs could reduce pathological biomechanics associated with PHP, with reduction of knee and forefoot motion in the frontal and transverse planes which have been associated with reductions in the load in the plantar fascia. After one month follow up, the CFOs decreased pain intensity and increased foot function, and showed significant improvements in temporal and spatial parameters of gait. Therefore, this study offers new insights into the action of CFOs and supports their use as an intervention for people with PHP.

CRediT authorship contribution statement

All authors agreed to be accountable for all aspects of the work, critically revised the article for important intellectual content, and approved the final manuscript to be published. Dr Harutaichun contributed to the conception and design of the study, acquisition of data, analysis and interpretation of data as well as writing of manuscript. Dr Vongsirinavarat contributed to the conception and design of the study, analysis and interpretation of data as well as editing of manuscript. Mr Sathianpantarit and Dr Thong-on contributed to the acquisition of data and review of manuscript. Dr Richards analyzed and interpreted data as well as editing of manuscript.

Patient and public involvement

Participants were not involved in the design of the study or in the interpretation or translation of the study findings.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availbility

All data relevant to the study are included in the article or are available as supplementary files. Please ensure that no patient-identifiable data are available.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.gaitpost.2023.08.003.

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