

Effect produced on ground reaction forces by a prefabricated, weight-bearing and non-weight-bearing foot orthosis in the treatment of pronated foot

Pilot study

Gabriel Gijon-Noguero, PhD^a, Inmaculada Palomo-Toucedo, PhD^b, Alejandro Gil-Tinoco, BsC^c, Ana Belen Ortega-Avila, PhD^{a,*}, Pedro Vicente Munuera-Martínez, PhD^b

Abstract

Background: The aim of this study is to explore the changes in ground reaction force (GRF) produced by custom-made weight-bearing and nonweight-bearing foot orthoses and by a prefabricated foot orthosis, in the control of the pronated foot.

Methods: Thirty-nine participants were recruited. All were in good health, aged 18 to 25 years, and presented pronated foot. Three different types of foot orthosis were studied: prefabricated, weight-bearing, and nonweight-bearing.

Results: No significant differences were observed in the phases of the gait cycle between the prefabricated, the weight-bearing, and the nonweight-bearing foot orthoses.

Conclusions: Neither prefabricated insoles nor custom-made orthoses (weight-bearing or nonweight-bearing) modified GRF.

Abbreviations: ANOVA = analysis of variance, BW = body weight, CEUMA = Ethic Committee of the University of Málaga, FPI = foot posture index, GRF = ground reaction forces, SD = standard deviation, STJ = subtalar joint.

Keywords: foot orthosis, gait analysis, ground reaction force, pronated foot

1. Introduction

From an anatomical perspective, the foot is a complex group of bones and muscles.^[1] In its biomechanical function, it is a marvellous structure. The foot must perform diverse functions at specific times during the gait cycle; on one hand, it must adapt to the ground surface and simultaneously facilitate the body's shock-absorbing mechanism; on the other hand, it functions as a rigid lever to propel the body across the ground. The normal

(structurally nondeformed) foot is adequately prepared to perform these functions.^[2]

In a closed kinematic chain, the motions of the foot are composed of 3 cardinal plane components: subtalar eversion, ankle dorsiflexion, and forefoot abduction.^[3] These 3 distinct motions occur simultaneously during the pronation phase.^[4] Numerous pathologies are caused by biomechanical problems arising from the forces that interact with the foot and force it to make compensatory movements, thus generating pain and sometimes long-term deformity.^[5] Excessive or prolonged pronation of the foot (specifically, of the subtalar joint [STJ]) may be related to the development of pathologies of the lower limb, produced by a pathomechanical dynamic coupling, from distal to proximal, between the foot, knee, and hip.^[6,7] This disorder may also give rise to overuse injuries affecting the lower back, hip, knee, lower part of the leg, ankle, and foot.^[8,9]

Many strategies have been developed to treat pronation, including heel pads,^[10] customised orthosis,^[11] low-dye taping,^[12] night splints,^[13] and extracorporeal shock wave therapy,^[14] all of which have been evaluated in randomized trials. The main limitations of the available literature on biomechanical foot problems are the lack of consensus as to what actually constitutes a "foot problem" and the variety of treatments that have been proposed.^[15]

Among conservative treatments for abnormal foot function, 1 of the most common is the use of a functional foot orthosis,^[16] which, according to previous research on the effects of foot orthotics, has produced many successful outcomes in the treatment of pronated or flat feet.^[17] Orthoses are intended to alter the function of the joints of the foot and lower limb during weight-bearing activities, often placing the STJ in a neutral

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^a Department of Nursing and Podiatry, University of Malaga, Malaga,

^b Department of Podiatry, University of Seville, Seville, ^c Musculoskeletal Department North Tee and Hartlepool, NHS Hartlepool, UK.

* Correspondence: Ana Belen Ortega-Avila, Department of Nursing and Podiatry, Faculty of Health Sciences, University of Malaga, Arquitecto Francisco Peñalosa 3, Ampliación de Campus de Teatinos, Malaga 29071, Spain (e-mail: anaortavi@uma.es).

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position. Some studies have reported that orthoses can achieve significantly reduced peak pressure and force in comparison with shoe only.^[18] Others have observed that young adults with flatfoot may present increased ankle joint angles in the mid-stance of the gait cycle after using orthotics.^[19,20] Functional foot orthoses, or variants of the original design, comprise the vast majority of plantar orthotics employed by podiatrists.^[21] In this respect, approaches that have been proposed include weight-bearing casts obtained by means of a plaster bandage, phenolic foam or other materials, or by fitting plastic materials directly onto the patient's foot.^[22,23] Although these techniques have been in use for many years, to our knowledge, no studies have compared the effects produced by these types of orthosis on pronatory forces. Neither has any study sought to compare orthoses obtained from a weight-bearing cast with those obtained from the direct fitting of plastic materials to the patient's foot, and with prefabricated foot orthoses.

The aim of the present study was to observe whether prefabricated orthoses reduce ground reaction forces (GRFs) in comparison with custom-made insoles (weight-bearing or non-weight-bearing), in response to an excess of pronatory forces. The null hypothesis is that custom-made foot orthoses do not provide statistically significant differences in ground reaction forces magnitude when comparing with prefabricated foot orthoses.

2. Method

2.1. Protocol and registration

This study was carried out in full accordance with the Declaration of Helsinki on ethical principles for medical research involving human subjects, and was approved by the Ethics Committee of the University of Málaga (CEUMA 97/2015H) (Spain).

2.2. Design

The design was a cross-sectional study (pilot study).

2.3. Subjects

In all, 39 participants were recruited from students of the University of Malaga, from January, 2014 to June, 2015. All subjects were at least 18 years old and were able to follow the study instructions.

Inclusion criteria were that the participants should be healthy, aged 18 to 25 years, present pronation, have a foot posture index (FPI) score >6 points, and not have used an insole previously.

Exclusion criteria were previous lower limb surgery, pregnancy, a self-reported history of vertigo, malignancy, stroke, or other condition that might impair vestibular function, evidence of abnormal gait patterns, lower limb deformities, or foot pain.

In accordance with the study protocol (Fig. 1), a total of 39 subjects were analyzed. Of these, 21 had FPI >6 and were assigned to the intervention group. Each subject received 3 types of foot support (prefabricated insole, weight-bearing insole, and non-weight-bearing insole). The order of intervention was randomized by software, with a 1-week washout period between each of the 3 interventions and 1 week of use before the measure, in each case.

2.4. Intervention

Information regarding the intervention and the patient's demographic and health-related characteristics, together with the FPI and the biomechanical and clinical data, was compiled by

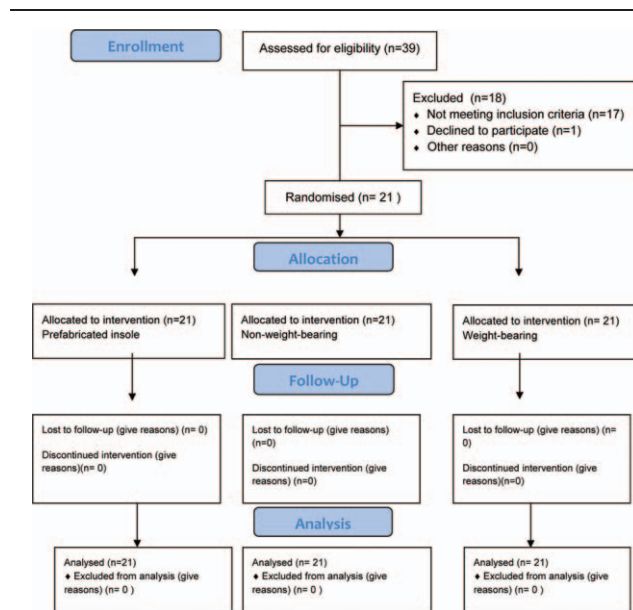


Figure 1. Consolidated standards of reporting trials (CONSORT) 2010 flow diagram.

an experienced podiatrist (IP). Baseline data were taken in all cases as walking with no intervention, wearing a standard shoe.

Three different types of insole were used for the study. The first was a prefabricated Sidas Gel 3D 2012 (Shore A 23) with a cushioned heel and metatarsal and a high-density ethylene vinyl alcohol structure for midfoot control, in the appropriate size for each study participant (Fig. 2A). In addition, 2 custom-made insoles were analyzed. To create them, a cast of the foot of each participant was obtained, using phenolic foam and with the subtalar joint placed in a neutral position and the forefoot plantar plane parallel to the floor. The negative moulds of phenolic foam were then filled with liquid plaster to obtain a positive cast of the foot on which to make the foot orthosis. The orthoses were made with 3-mm polypropylene and extended from the heel to just behind the metatarsal heads (Fig. 2B). The positive plaster cast was then introduced into a vacuum, with the plantar surface upwards. A 3-mm polypropylene sheet was heated to 180 degrees, until it became transparent (3–4 minutes), when it was inserted into a vacuum press to form the orthosis. A 3-mm polyethylene foam sheet was then heated and placed on the upper surface of the positive cast just before the polypropylene, so that the 2 materials adhered by heat and pressure. For the later removal of surplus material, the orthosis was marked with a calcaneal line parallel to the dorsal surface of the positive cast and 10 to 15 mm above the support surface level; in addition, a point was marked just below the navicular tuberosity, representing the maximum height of the orthosis on the medial side, and a distal line was drawn to join the points just proximal to the metatarsal heads, ending at the proximal edges of the first and fifth metatarsal heads. The surplus material was removed with a polishing machine.^[24]

The other method used was that of direct moulding (DM), described by Gijon-Nogueron et al^[22] in 2013, in which the insole is directly moulded to the foot of the patient, using a vacuum system. During this process, the material is heated to be moulded on the plantar aspect of the nonweight-bearing foot controlling the subtalar joint in its neutral position. This gives a maximum adaptation of the insole to the medial longitudinal arch and good



Figure 2. Type of foot orthosis analyzed (Figura 2A. Prefabricated Insole; Figura 2B. Weight-bearing; Figura 2C. Non-Weight-Bearing).

alignment of the metatarsal heads in the frontal plane. All these structures are controlled using the central stabilizing element^[2,3] and a forefoot-stabilizing element, which jointly regulate the movement of the foot from the heel contact phase to the toe-off phase. The following materials are used to make these orthoses: polyester resins with a combination of 1.2 mm Podiaflex and 1.2 mm Podiaflux for the hindfoot and midfoot, and 0.8 mm Podiaflex for the forefoot; the cover is composed of polyethylene ethylene vinyl alcohol with 30 Shore A hardness and 148 kg/m³ density (Fig. 2C).

2.5. Procedure

The subjects were asked to walk, wearing the same type of shoes (Newfeel Oxylane sport shoes) at their 'most comfortable speed' (ie, self-selected speed) along an 8-m walkway fitted with a Bertec FP4060-07 force plate at the midpoint of the walkway (Bertec Corporation, Columbus, OH) to record the GRF. The GRF along vertical (z), antero-posterior (y), and lateral-medial (x) axes, time to peak, and vertical loading rate^[2,5] were then calculated. The gait cycle analysis was performed using the divisions established by Perry^[6] as follows: 0% to 2% initial contact, 3% to 12% response to load, 13% to 31% mid-stance, 32% to 50% terminal stance, 51% to 62% preswing, 63% to 75% initial swing, 76% to 82% mid-swing, and 83% to 100% terminal swing. All GRF values were normalized with respect to the body weight ("BW") and "BW \times height," respectively. After each such trial, the subject's starting position was adjusted to maximize the number of steps landing on the force plates. The

instructions given were to "walk as you normally would until you reach the end line" always in the same direction. If a participant appeared to adjust their step during the walking trial to target a force plate, clear explanations were provided regarding the importance of walking in their usual manner during the tests and of not targeting the force plates. Five "appropriate" trials were collected for each limb. A trial was considered "appropriate" if a single foot landed on the force plate and in its entirety. This was determined through visual observation by an assistant standing on a platform 3 feet away from the force plates, and also by video recording. When necessary, rest breaks were taken between the trials to ensure that the participants were not fatigued and that the trial reflected their true self-selected speed. The force values recorded were divided by the participant's bodyweight, using a Microsoft Excel macro, to normalize the data and thus facilitate comparisons between individuals.^[2,6]

2.6. Sample size

The sample size was determined by application of the EPIDAT software program, using as a reference a similar study by Prachgosin et al,^[17] to identify the true difference in the means of the force plate scores in the x axis between the 3 treatments. For a significance level of .05 and a power of 80%, we calculated that 20 subjects would be needed to obtain a significant difference at the 95% level between the prefabricated insole, a polypropylene weight-bearing insole, and a resin nonweight-bearing insole, with a predicted effect size of 0.8.

2.7. Statistical analysis

To preserve the independence of data,^[27] and taking into account the strong correlation between GRF scores for left and right feet achieved in previous studies,^[17,20] although both feet were measured, for further statistical analysis only 1 foot (the right, chosen at random) was included in the statistical analyses.

The data were analyzed using IBM SPSS v.23 statistical software (SPSS Science, Chicago, IL). Normality of the distribution was tested by the Shapiro-Wilk tests. A repeated-measures analysis of variance (ANOVA) was used to assess the three insoles. The ANOVA results were expressed as differences of the means, confidence intervals (CIs), and *P* values. An intention-to-treat analysis (the last observation carried forward) was performed for all participants. Differences were considered to be statistically significant at *P* < .05.

2.8. Ethical approval

Institutional review board that approved the protocol for the study was Medical Research Ethics Committee of University of Malaga (CEUMA-2015-097-H).

3. Results

Of the 39 participants initially recruited, 21 (8 male and 13 female) were finally selected according to the criteria of FPI >6 points. Their mean age was 22.4 years (SD 1.5). The mean FPI score was 8.47 (SD 0.5) for both feet, and the mean body mass index was 20.42 (SD.23) (Table 1).

The mean force plate scores in the phases of the gait cycle for the nonweight-bearing foot orthosis were similar to those recorded for the prefabricated and weight-bearing orthoses

Table 1

Characteristics of the sample according with BMI, age, FPI score, and sex.

	Mean	SD	95% CI	
Age, y	24.71	3.55	23.10	26.33
FPI right	8.62	1.36	8.00	9.24
FPI left	8.29	1.49	7.61	8.96
Weight, kg	64.12	11.36	58.95	69.29
Height, cm	168.62	8.76	164.63	172.61
BMI, kg/m ²	22.45	2.85	21.15	23.75
Sex (male/female)	9/12			

BMI=body mass index, CI=confidence interval, FPI=foot posture index.

(Table 2), with little or no difference between the gait cycles and three spatial axes (Fig. 3A–C).

Among the 3 treatments compared, no significant, generalized differences were observed, although in the second phase of the gait cycle, there was a difference between the nonweight-bearing and the prefabricated orthoses (difference of the mean: 8.05 N and *P* = .02), in the Fx axis in the right foot and in the y axis in the fourth and sixth phases between the nonweight-bearing and the weight-bearing orthoses (difference of the mean: 819.96 N and *P* = .05, and 25.59 and *P* > .001).

4. Discussion

The aim of this study was to determine the effect of different types of insole on GRF in the pronated foot, as many studies have associated this biomechanical impairment with musculoskeletal problems.^[28] The results obtained suggest that the 3 different

Table 2

Characteristic of the simple in the difference gait phases by Perry^[6].

Gait phase	Axis	Prefabricated			Weight-bearing			Nonweight-bearing					
		Mean (n)	95% CI	SD	Mean (n)	95% CI	SD	Mean (n)	95% CI	SD			
0	Fx	0.76	−0.34	1.86	1.99	1.00	−0.41	2.41	2.55	0.94	−0.38	2.27	2.39
	Fy	3.10	0.78	5.43	4.19	4.50	−0.34	9.34	8.73	5.27	1.77	8.76	6.31
	Fz	14.10	11.25	16.94	5.14	14.36	11.19	17.54	5.73	12.14	10.19	14.08	3.51
1	Fx	13.99	9.78	18.20	20.08	10.35	5.99	14.70	20.81	11.79	7.31	16.26	21.37
	Fy	75.63	62.55	88.70	62.42	76.70	62.19	91.22	69.31	77.68	63.13	92.22	69.45
	Fz	500.05	452.16	547.94	228.65	500.79	449.86	551.71	243.14	515.65	464.95	566.34	242.03
2	Fx	−39.66	−43.88	−35.43	24.82	−42.11	−46.10	−38.12	23.43	−47.71	−51.81	−43.61	24.09
	Fy	154.28	147.47	161.09	40.02	157.15	149.32	164.97	45.99	161.57	154.32	168.81	42.55
	Fz	995.65	975.00	1016.31	121.32	983.22	963.17	1003.28	117.84	1011.36	991.72	1031.01	115.41
3	Fx	−34.53	−37.22	−31.83	16.70	−34.08	−36.59	−31.58	15.52	−37.86	−40.60	−35.12	16.97
	Fy	66.65	62.44	70.86	26.09	63.86	59.68	68.05	25.92	65.02	60.41	69.62	28.53
	Fz	902.45	891.07	913.83	70.52	891.52	879.08	903.96	77.09	911.57	891.73	931.42	122.99
4	Fx	−28.54	−31.80	−25.27	15.59	−27.57	−30.98	−24.16	16.28	−30.93	−34.01	−27.85	14.69
	Fy	1.56	−3.03	6.16	21.93	0.77	−2.96	4.50	17.81	−1.32	−5.70	3.06	20.92
	Fz	904.95	895.20	914.71	46.57	879.36	868.80	889.92	50.43	894.35	875.85	912.84	88.30
5	Fx	−42.04	−45.28	−38.80	16.73	−40.32	−44.59	−36.05	22.07	−43.91	−47.65	−40.17	19.34
	Fy	−73.39	−80.40	−66.39	36.18	−73.50	−79.92	−67.09	33.15	−80.97	−88.02	−73.93	36.41
	Fz	1014.41	1000.64	1028.17	71.13	1002.80	992.07	1013.53	55.44	1030.70	1011.50	1049.90	99.20
6	Fx	−31.61	−36.81	−26.40	24.87	−33.12	−39.11	−27.13	28.59	−33.30	−38.82	−27.78	26.36
	Fy	−167.39	−174.47	−160.32	33.78	−162.79	−169.66	−155.93	32.80	−174.24	−180.91	−167.57	31.84
	Fz	906.32	874.66	937.98	151.15	910.59	879.49	941.70	148.51	923.81	888.08	959.53	170.57
7	Fx	1.02	−0.98	3.02	9.53	1.41	−0.53	3.35	9.26	1.18	−0.69	3.04	8.91
	Fy	−61.22	−72.70	−49.75	54.80	−70.80	−82.94	−58.65	58.00	−66.88	−79.43	−54.32	59.94
	Fz	217.50	178.93	256.06	184.12	241.92	199.97	283.86	200.27	219.08	179.56	258.59	188.65

CI=confidence interval, N=Newton, SD=standard deviation.

Fx, Fy, Fz are the GRF along vertical (z), antero-posterior (y), and lateral-medial (x) axes.

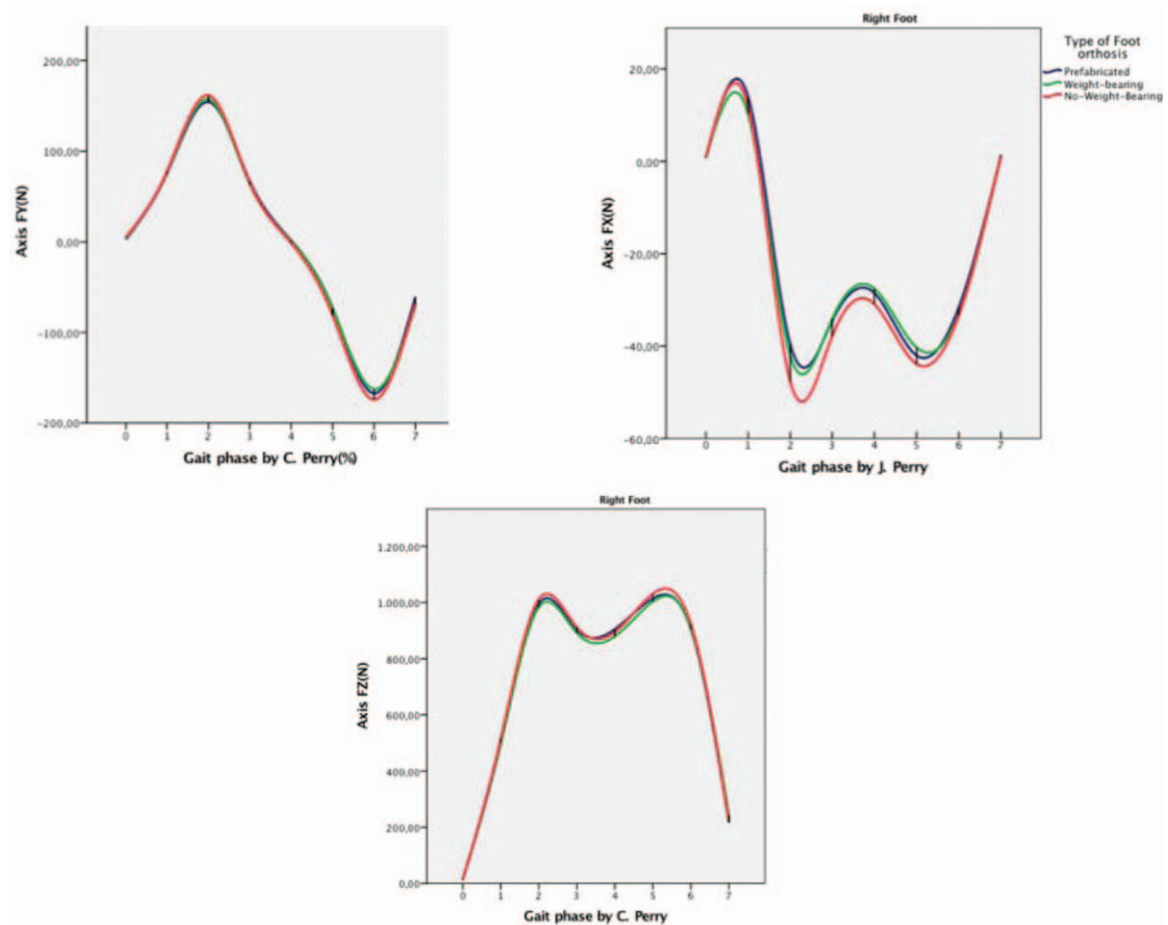


Figure 3. (A–C) Time-normalized sample traces of the ground reaction forces of a normal subject during walking. Reaction forces and impulse area in all axes are shown.

types of foot orthoses that were analyzed behaved in a similar way when the GRF acted on them, and therefore presented minimal changes. With the data obtained in the present study we cannot completely reject the null hypothesis. Nevertheless, at a statistical level, the nonweight-bearing insoles produced a noticeable change at the F_x axis, whereas there was great similarity between the F_y and F_z axes.

Various studies have analyzed the effects of different types of foot orthoses and flatfoot on the gait cycle,^[29] with respect to the eversion movement in the ankle joints or the rotation movement of the tibia or hip.^[30] Others have considered the effects of foot orthosis on stability and unipodal support, highlighting its effectiveness, with a reduction in the eversion deformity and a return to the natural position.^[31,32] However, regarding the GRF, very limited evidence has been reported. Nevertheless, our results in this respect are in line with those of Prachgosin et al,^[17] who analyzed kinetic and kinematic data for 7 flatfoot and 13 normal-foot subjects, comparing barefoot condition, shod without foot orthoses, and shod with custom-made foot orthoses made from casts obtained using the foam box technique. These authors observed significant differences in medial longitudinal arch movement during shod walking among the participants with normal foot, flatfoot with no orthosis, and flatfoot with orthosis. However, the center of pressure excursion and the GRF in the medial-lateral direction, the part of the medial longitudinal arch eversion in the calculation, did not increase significantly in the

flatfoot subjects after walking with the custom-made foot orthoses.

Prefabricated, weight-bearing, and nonweight-bearing insoles all had similar effects on GRF, which is in line with the findings of Redmond et al,^[33] who showed that prefabricated and customized insoles have similar mechanical characteristics, as regards their effect on plantar pressures. In the latter study, however, the customized foot orthoses were obtained by the standardized prone-casting protocol to obtain neutral impression casts. Similar data were reported by Bonanno et al,^[34] who used a medial heel skive with a 6 mm wedge to reduce midfoot forces.

Regarding stability and the decrease in GFR, very few studies have examined different types of orthoses,^[31] focusing instead on custom-made orthoses combined with footwear, and reporting no significant differences in relation to the anteroposterior or mediolateral axis of the foot.

Although most previous studies measured changes in plantar pressures in the pronated foot,^[33,34] we believed that the GRF might modify the force exerted by insoles on the foot. However, these forces could be produced within the joint, and in many cases these movements are poorly understood due to the difficulty of measuring them.^[35]

This consideration led us to question why many of the patients treated with foot orthoses report improvements and/or a better quality of life. One reason for this could be a comfort effect of the insole, creating a relaxation of the leg muscles and less muscle

recruitment in the affected area.^[36] With pronated feet, there is often tension in the muscles of the sole and the fascia, which are severely stressed in the middle stance during flat-surface walking and in maintaining the bow shape of the normal sole. The simple course of time or other variables might also influence the improvement observed, although Seo et al^[19] reported that orthotics can be used for foot alignment and support, the prevention and correction of foot deformities, and improved foot function.^[19]

In this preliminary analysis, we evaluated healthy subjects with no associated pathology. The study population had more women than men, and this imbalance may have affected the results obtained, as it has been suggested that women tend to pronate more in the midfoot area.^[37] Obviously, the presence of a painful pathology may alter the gait, and this aspect is a limitation of the present study. As an area for future study, we intend to examine the influence of different types of insole on subjects with plantar pain. Moreover, this study contains a 3D analysis of the movement in the 3 combined planes, which is how the pronation movement is defined, and not an individual analysis of each of the 3 axes. Following the studies in this respect performed by Redmond et al^[33] and Nigg et al,^[38] further research is needed to determine the effect of the orthoses not only in the kinetics or kinematics, but also in the effects on the tissues involved and on tissue stress,^[39] and other areas yet to be analyzed.

Although the question should be addressed with great caution, we conclude that GRF may not be affected by a foot orthosis, and therefore that the latter should be viewed as 1 more variable to be taken into account in orthotic treatment—no more, no less—because it has not been proven to be a determinant factor in improving the patient's condition. The findings of this study lead us to speculate whether foot movement should be controlled before its appearance—a concept that would encompass the use of plantar supports fabricated using nonweight-bearing techniques.

Another factor that should be taken into account in the analysis is that of the shoes worn in the study. Those used in the present study were trainers, which have certain features that make them “comfortable.”^[40] Sports trainers, and especially running trainers, are commonly designed with high shock absorption and cushioning characteristics that reduce the impact from GRF more than normal shoes, and therefore foot orthoses may derive greater benefit in them.^[41]

Another aspect to be borne in mind is the fact our subjects did not present muscle fatigue, and so we were unable to examine the foot behavior in response to certain pathologies, as active control of the muscles of the foot is fundamental to its proper function, especially in the pronated foot.^[42]

Impact forces are partially absorbed by the musculoskeletal system, but this attenuating capacity is reduced when fatigue is present.^[43] This factor, too, could influence the differences arising from different treatments.

5. Conclusions

Like prefabricated insoles, custom-made nonweight-bearing and weight-bearing orthoses do not significantly modify ground reaction forces. Further research, with movement analysis systems, should be undertaken to confirm these results.

Author contributions

Formal analysis—ABO-A; investigation—ICP-T, AG-T, and PVM-M; methodology: GG-N and ICP-T; supervision—ABO-A and

PVM-M; validation—GG-N; writing original draft—GG-N, ICP-T, ABO-A, and PVM-M.

Formal analysis: Ana Belen Ortega-Avila.

Investigation: Inmaculada Concepcion Palomo-Toucedo, Alejandro Gil-Tinoco, Pedro Vicente Munuera-Martinez.

Methodology: Gabriel Gijon-Nogueron, Inmaculada Concepcion Palomo-Toucedo.

Supervision: Ana Belen Ortega-Avila, Pedro Vicente Munuera-Martinez.

Validation: Gabriel Gijon-Nogueron.

Writing – original draft: Gabriel Gijon-Nogueron, Inmaculada Concepcion Palomo-Toucedo, Ana Belen Ortega-Avila, Pedro Vicente Munuera-Martinez.

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