Impact accelerations during a prolonged run using a microwavable self-customized foot orthosis

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Abstract

Purpose: The use of custom-made foot orthoses has been associated with numerous benefits, such as decreased impact accelerations. However, it is not known whether this effect could be due to better customization. **Objective:** The present study analyzed the effects of a microwavable prefabricated self-customized foot orthosis vs. a prefabricated standard one on impact accelerations throughout a prolonged run. **Methods:** 30 runners performed two tests of 30 min running on a treadmill, each one with a foot orthosis condition. Impact acceleration variables of tibia and head were recorded every 5 min. **Results:** Microwavable self-customized foot orthosis significantly increased tibial peak acceleration (min 1: *P*=.009, ES=0.3, and min 5: *P*=.035, ES=0.2), tibial magnitude (min 1: *P*=.030, ES=0.2, and min 5: *P*=.026, ES=0.2) and shock attenuation (min 1: *P*=.014, ES=0.2, and min 5: *P*=.040, ES=0.2) in the first instants, and tibial rate throughout the entire run (*P*<.05, ES=0.3 - 0.5). However, it was more stable throughout 30 min running (*P*<.05). **Conclusion:** These results show that the different characteristics of the materials of the foot orthoses (composition, stiffness, hardness and thickness of the layers) could have a greater weight on impact accelerations than a better customization.

WC: 192

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Introduction

Running is an activity in continuous growth of participation (Mercer & Horsch, 2015), but linked to a high rate of injuries (Francis et al., 2019; van Gent et al., 2007). These injuries usually occur in the lower limb and are supposed to be related to accumulative loading due to the cyclic and repetitive character of the run (Abt et al., 2011; Bowser et al., 2018; van Gent et al., 2007). Feet contact with the ground about 600 times for each kilometer run and a rapid deceleration occurs in the lower limb in each contact, generating a shock wave that is transmitted from the foot to the head (García-Pérez, Pérez-Soriano, Belloch, Lucas-Cuevas, & Sánchez-Zuriaga, 2014; Lucas-Cuevas, Camacho-García, et al., 2017; Windle, Gregory, & Dixon, 1999). Although our musculoskeletal system is prepared to absorb this shock (Derrick, Dereu, & McLean, 2002; Mercer, Vance, Hreljac, & Hamill, 2002), this ability could be reduced due to the fatigue of the musculoskeletal system produced by the repeated and accumulated exposure to these impacts during a prolonged run (Mizrahi & Daily, 2012). In this sense, previous studies have observed that impact accelerations increase throughout a prolonged run, and may cause injuries such as tibial stress fractures (Sheerin et al., 2019).

Hence, various strategies have been suggested to help attenuate and reduce these accelerations such as: footwear (Chambon et al., 2014), compressive garments (Lucas-Cuevas et al., 2015), or foot orthoses (Lucas-Cuevas, Camacho-García, et al., 2017; O'Leary, Vorpahl, & Heiderscheit, 2008). Focusing on the foot orthoses, it is believed that they could reduce impact accelerations by introducing a cushioning element between the ground and the foot (Mills et al., 2010). However, few studies have yet investigated the effect of foot orthoses on accelerations during running, and their mechanism of action remains unclear (Jimenez-Perez et al., 2019; McMillan & Payne, 2008). In addition, the effect of foot orthoses on impact accelerations has usually been studied through running trials (Butler et al., 2003; Laughton et al., 2003; O'Leary et al., 2008) or after a short continuous run (Lucas-Cuevas, Camacho-García, et al., 2017), when it would be interesting to investigate what happens during the evolution of a prolonged run, which offers a more real vision of the recreational runners' usual practice (MacLean, Van Emmerik, & Hamill, 2010).

In this context, new generations of foot orthoses have emerged due to the apparition of new technologies and materials (Jimenez-Perez et al., 2019): wearables foot orthoses, foot orthoses energy generators, foot orthoses created from 3D scanning with a smartphone, or microwavable self-customized foot orthoses. The last ones are considered a type of low-cost prefabricated foot orthosis made with thermoformable materials, which allows its customization by the user with a home microwave in his/her own home (Jimenez-Perez et al., 2019). The use of foot orthoses with customization has been associated with improved comfort (Lucas-Cuevas, Perez-Soriano, Priego-Quesada, & Llana-Belloch, 2014), reduced plantar pressure (Lee et al., 2012) or decreased impact accelerations (Lucas-Cuevas, Camacho-García, et al., 2017). Specifically, the custom-molded shape was observed to be the most important design factor in reducing peak plantar pressure (Cheung & Zhang, 2008). Nevertheless, it is not known whether reductions in impact acceleration could also be due to better customization. In this sense, the effects of these new products on running biomechanics and impact accelerations need to be investigated, and even more during a prolonged run.

Therefore, the aim of the present study was to analyze the effects of a microwavable prefabricated self-customized foot orthosis in comparison with a prefabricated standard one without customization on impact accelerations throughout 30 min prolonged run. We hypothesized that the use of microwavable self-customized foot orthoses would present lower impact accelerations than prefabricated standard ones.

Methods

Participants

30 recreational runners: 15 males and 15 females (Mean (standard deviation): age 32 (7) years, body mass 62.5 (9.9) kg, height 1.69 (0.08) m, running training distance 32.3 (12.0) km⁄week, VO_2/kg 52 (6) ml/min/kg) took part voluntarily in the study. Inclusion criteria included no history of lower extremity injuries within the last six months, no previous use of foot orthoses, a training routine of at least 20 km/week, and a performance between 40-55 min over a distance of 10 km. The study procedures complied with the Declaration of Helsinki and were approved by the University Ethics Committee (approval number H1457612626675). All participants provided written informed consent.

Foot orthosis conditions

Participants carried out the study under two different randomized conditions on different days (**TABLE 1**): (1) prefabricated standard foot orthoses (SFO) without customization; and (2) microwavable prefabricated self-customized foot orthoses (MCFO). Both foot orthoses were chosen only according to runners' foot size. In accordance with the manufacturer's instructions, the MCFO were customized to each participant by heating them in a home microwave at medium power for 40 s. Then, runners were instructed to put on their footwear with MCFO inside, to remain static standing for 2 min, and to walk for at least 1 h.

****Table 1 near here****

Protocol

First, runners performed a maximum incremental test on a treadmill (Trackmaster, Norav Medical Ltd., Yokneam, Israel) to determine the maximum oxygen consumption (VO_{2max}) speed, through gas exchange analysis (Cortex Metalyzer 3B-R3, Leipzig, Germany).

Wasserman's workload protocol (Wasserman et al., 1999) was followed, starting walking at a speed of 4 km/h and increasing 1 km/h every min until the runner's exhaustion. After that, runners carried out two similar running tests, separated by two weeks, each one with a different foot orthosis condition, previously randomized. These tests consisted of running 30 min on a treadmill (Excite Run 900, TechnoGymSpA, Gambettola, Italy) at 75% of their VO_{2max} with 1% of slope. Before this, participants warmed up for 6 min of running increasing the speed every 2 min progressively, until reaching the speed set for the 30 min run. Throughout the 30 min running, impact acceleration variables were measured for 15 s, every 5 min (1', 5', 10', 15', 20', 25', 30'); and the rating of perceived exertion (RPE) between 6 and 20 points (Borg, 1982) and the heart rate (HR) (Polar V800, Polar Electro Oy, Kempele, Finland) were reported during the last min to control intensity level. Before each test, the participants trained for two weeks progressively with the foot orthosis condition assigned as adaptation period (Butler et al., 2003; Laughton et al., 2003). Moreover, the runners wore their own running footwear, and the same for all tests and adaptation periods, in order to produce no further changes in their customary running condition (Lewinson et al., 2016).

Data collection and analysis

Impact accelerations were measured using two lightweight tri-axial accelerometers (MEMS in MPU-60X0, BlauTic®, Valencia, Spain; total mass: 2.5 g; dimensions: 40 mm × 22 mm × 12 mm; sampling frequency 415 Hz). One of the accelerometers was placed in the distal anteromedial aspect of the non-dominant tibia, and the other in the center of the forehead, always aligning the vertical axis parallel to the long axis of the shank (Lucas-Cuevas, Encarnación-Martínez, Camacho-García, Llana-Belloch, & Pérez-Soriano, 2017). Vertical acceleration data were filtered (8-order low-pass digital Chebyshev type II filter, stop-band edge frequency 120 Hz, stop-band ripple 40 dB) and analyzed using Matlab (Version Matlab

R2017a, The Math Works Inc., Natick, MA, USA). The impact acceleration variables calculated from the acceleration signal were: head and tibia peak acceleration (maximal amplitude), acceleration magnitude (the difference between the maximum and the minimum peak), acceleration rate (slope from ground contact to peak acceleration, calculated as the 20-80% of the acceleration peak amplitude), and shock attenuation (reduction in peak acceleration from the tibia to the head as a percentage of the tibial peak acceleration).

Statistical analysis

A statistical software (SPSS 23.0, IBM, Armonk, USA) was used for statistical analysis. Normality (Kolmogorov-Smirnov test) and sphericity (Mauchly Sphericity test) were verified (P>.05), and descriptive statistics were extracted. Data were reported as mean and 95% confidence intervals (95%CI). Then, two-way repeated-measures ANOVAs with foot orthoses with two levels (SFO, MCFO) and time with seven levels (1', 5', 10', 15', 20', 25', 30') as intra-subject factors and impact acceleration variables as dependent variables were performed. For the significant ANOVA model (P<.05), Bonferroni correction post-hoc test was carried out. A student t-test was performed to analyze the differences in the RPE and HR between foot orthosis conditions. Significance level was set at α=.05. For the pair significant differences (P<.05), Cohen's effect size (ES) was computed and classified as small (ES 0.2–0.5), moderate (ES 0.5–0.8) or large (ES > 0.8) (Cohen, 1988).

Results

Effect of the foot orthoses on impact accelerations

The use of foot orthoses did modify impact acceleration variables (**FIGURE 1**). In this sense, MCFO showed greater tibial peak acceleration and tibial magnitude compared to SFO at min 1 and min 5 (tibial peak acceleration: min 1: *P*=.009, ES=0.3, and min 5: *P*=.035, ES=0.2; tibial magnitude: min 1: *P*=.030, ES=0.2, and min 5: *P*=.026, ES=0.2). Higher shock attenuation was observed for MCFO condition in both instants (min 1: *P*=.014, ES=0.2, and min 5: *P*=.040, ES=0.2) (**FIGURE 2**). In addition, MCFO showed significant greater tibial acceleration rate at every min (*P*<.05, ES=0.3 - 0.5). On the other hand, in head variables, no differences between foot orthoses were observed in the magnitude (*P*>.05), but peak acceleration was reduced with MCFO at min 10 (*P*=.022, ES=0.2). Inversely, an increase with MCFO at the same instant was observed in acceleration rate (*P*=.018, ES=0.2).

Differences between the measurement instants were observed only in SFO. Significantly greater tibial magnitude was observed when running with SFO between the min 15, 20, 25 and 30 compared to the initial measurement (min 1) (*P*=.014, ES=0.2; *P*=.004, ES=0.3; *P*=.009, ES=0.3; *P*=.016, ES=0.3, respectively), and between the min 20 compared with min 5 and 10 (*P*=.029, ES=0.3 and *P*=.002, ES=0.2, respectively). In addition, shock attenuation with SFO was significantly greater at min 15 compared with min 10 (*P*=.048, ES=0.1).

****Figure 1 near here****

****Figure 2 near here****

Effect of the foot orthoses on rating of perceived exertion and heart rate

Participants reported similar RPE for both foot orthosis conditions (SFO vs. MCFO: 14.62 points (95%CI: 13.69, 15.55) vs. 14.76 points (95%CI: 13.84, 15.68), *P*>.05), considering the tests as ‘Hard’. Likewise, final heart rate was similar in both tests (SFO vs. MCFO: 174.86 bpm (95%CI: 170.51, 179.20) vs. 176.25 bpm (95%CI: 172.15, 180.35), *P*>.05).

Discussion and Implications

The aim of the study was to analyze the effects of a microwavable prefabricated self-customized foot orthosis on impact accelerations during its use throughout 30 min prolonged run. Results showed an increase of tibial peak acceleration, tibial acceleration magnitude and shock attenuation with MCFO only in the initial instants of the run, and a greater tibial acceleration rate throughout the run. However, differences between time instants were only found with SFO.

The use of custom-made foot orthoses has been associated with numerous benefits, such as decreased impact accelerations (Lucas-Cuevas et al., 2014; Lucas-Cuevas, Camacho-García, et al., 2017). However, it is not known whether the customization of foot orthoses is related to the reduction of impact accelerations, among other effects. We hypothesized that the use of MCFO would present lower impact accelerations than SFO, however, results showed that tibial acceleration rate was greater with MCFO than with SFO throughout the 30 min run. This variable has hardly been studied, but it is of great interest because it may describe the capacity of the cushion structure to reduce the rate at which the impact acceleration is transmitted to the lower limb (Aguinaldo & Mahar, 2003). The only study (Lucas-Cuevas, Camacho-García, et al., 2017) that has analyzed this variable observed a reduction in the tibial acceleration rate with custom-made foot orthoses compared to prefabricated ones, but only at the beginning of the run. The differences in results between Lucas-Cuevas, Camacho-García, et al. (2017) and the present study suggest that the behavior of the different materials may have more influence on vibrations and accelerations than a best adaptation (Butler et al., 2003; O'Leary et al., 2008). In the present study, although the base composition of both foot orthoses was polyurethane foam, SFO presented Poron inserts (material designed to cushion) (Davidson, 2017) and MCFO had other compounds and materials (nonwoven polyester fabric with thermoplastic resins) to facilitate their adaptation but with reduced the cushioning capacity (Crabtree et al., 2009; Scherer, 2017). Other explanation for the greater accelerations of MCFO could be that by heating them to customize them, their materials became stiffer and less effective in the attenuation of applied forces (Brodsky et al., 2012). In addition, it has been observed that runners quickly adjust their leg-stiffness to changes in the stand surface (i.e. footwear and/or foot orthoses), with neuromuscular, kinematic and acceleration modifications (Nigg et al., 2017; Sheerin et al., 2019). In this sense, differences between both foot orthoses in the cushioning properties of the materials, the thickness of the layers (SFO: 5-6 mm vs. MCFO: 3-10 mm), or the stiffness and hardness (SFO: 20-30° vs. MCFO: 40-60°) could have altered the leg-stiffness, causing acceleration differences (Lucas-Cuevas, Camacho-García, et al., 2017; O'Leary et al., 2008).

In relation to tibial peak acceleration and acceleration magnitude, previous studies found no-modifications in these variables between rigid and soft foot orthoses with customization, compared with running without orthoses (Butler et al., 2003; Laughton et al., 2003), nor among prefabricated, custom-made and no-orthotic conditions (Lucas-Cuevas, Camacho-García, et al., 2017). Only O'Leary et al. (2008) observed reductions in tibial peak acceleration with the use of a cushioned prefabricated foot orthosis, regarding not wearing foot orthoses, because they were specially designed to cushion. In the present study, results showed an increase of tibial peak acceleration and acceleration magnitude with MCFO compared with SFO, but only in the first instants of the run (min 1 and 5). Despite increases in tibia acceleration, generally the accelerations in the head tend to keep within a constant and healthy range as protection (Derrick, Hamill, & Caldwell, 1998; Lucas-Cuevas et al., 2015; Mercer et al., 2002). According to this, only the SFO showed a greater head peak acceleration only in the min 10 of the run, and conversely a greater head acceleration rate was observed with MCFO at the same instant. Both results showed effect sizes below small and appeared in a timely and isolated manner, which makes interpretation difficult. Finally, it was found an increase in shock attenuation with MCFO in the first min of the run. This is an expected and logical result due to that the increase in tibial accelerations is related to greater shock attenuation to keep head acceleration constant (Derrick et al., 1998; Mercer et al., 2002; Verbitsky, Mizrahi, Voloshin, Treiger, & Isakov, 1998). On the other hand, although the adaptation period to the foot orthoses (2 weeks) was the one recommended by specialists when prescribing foot orthoses (Butler et al., 2003; Mündermann et al., 2004), it may not have been enough time for MCFO. While SFO have characteristics (i.e. shape, design and hardness) quite similar to the original insole of the shoe, which the runner is used to, MCFO are more different and could be a stranger element from the start. This could explain that at the beginning of the run MCFO need a few min to stabilize the pattern, but also the greater values observed in tibial acceleration rate.

Regarding the effect of running time, most studies that have analyzed the effects of foot orthoses on impact accelerations have done so in trials (Butler et al., 2003; Laughton et al., 2003; O'Leary et al., 2008) or at the beginning and at the end of a brief running protocol (Lucas-Cuevas, Camacho-García, et al., 2017). Nevertheless, it is necessary to carry out assessments in prolonged runs because they have a greater transfer to a real practice situation (Abt et al., 2011; Clansey et al., 2012). In this sense, the present study analyzes accelerations throughout a prolonged run and shows its evolution. The values of RPE (14 - 15 points) and HR (~175 bpm) obtained at the end of the run show that the intensity of the protocol was that corresponding to an aerobic training (Scherr et al., 2013), typical of a recreational runner. Furthermore, no-differences in these variables were observed between foot orthoses, so the results of accelerations cannot be justified by different levels of effort. Likewise, this shows that the level of effort was not influenced by the type of foot orthoses, as also found by Rubin et al. (2009).

During running, increases in the tibial magnitude were observed in min 15, 20, 25 and 30, compared to the initial instant; and increases in min 20 also with respect to 5 and 10, all with SFO. In addition, an increase was also found in min 15 compared to min 10 in the shock attenuation, with SFO. Consequently, it could be speculated that the MCFO acted with more stability throughout the entire run because no differences were found between instants. Several studies (Derrick, Dereu, & McLean, 2002; Mizrahi, Verbitsky, Isakov, & Daily, 2000; Reenalda, Maartens, Buurke, & Gruber, 2019) observed increases in tibial peak acceleration or shock attenuation as a result of the prolonged exercise, but without using orthoses, while others reported lack of modifications (Abt et al., 2011; Clansey et al., 2012; García-Pérez, Pérez-Soriano, Belloch, Lucas-Cuevas, & Sánchez-Zuriaga, 2014; Lucas-Cuevas, Camacho-García, et al., 2017), also without wearing foot orthoses, except Lucas-Cuevas, Camacho-García, et al. (2017). Differences in results between studies may be due to the level of fatigue achieved by runners (Abt et al., 2011; Clansey et al., 2012). Likewise, in this study, the intensity of the exercise may not have been so high as to cause a level of fatigue that induces further changes in acceleration.

The main limitation of this study was that the foot orthosis conditions were different in other characteristics (i.e. materials or thickness) apart from the customization, and they were not compared to a no-orthosis condition. However, this type of study was decided in order to be more similar to the real application in which the user goes to a store and must decide between prefabricated foot orthosis of different types and brands. In this sense, the results of the present study suggest important practical application on how new sports products, in this case foot orthoses, could alter sports biomechanics. The main practical advice obtained with our results is that customization is not the most important design factor in reducing impact accelerations and other characteristics of the foot orthoses may have a greater weight on accelerations.

Another limitation of the study was that each participant used their own footwear and the shoe cushioning system was not controlled. However, participants did use the same footwear, their own, for all tests, so the effect of the cushioning system was also the same for both orthoses. In addition own footwear contributes to the ecological validity of real-world study and does not interfere with the usual runner biomechanics (Lewinson et al., 2016; Reenalda et al., 2019). Other biomechanical variables related to impact accelerations such as leg-stiffness, neuromuscular activity or foot pronation (Grech et al., 2016; Nigg et al., 2017; Sheerin et al., 2019), remain to be studied and could provide more information and support the proposed hypotheses. Also, the longitudinal or prospective study of these products (foot orthoses) in future could be interesting to discover the modifications of their effects according to their use and their degradation (Dixon, 2007; O'Leary et al., 2008; Windle et al., 1999).

Conclusions

A microwavable prefabricated self-customized foot orthosis increases tibial accelerations and shock attenuation in the first instants of the run, and tibial acceleration rate throughout the entire run with respect to a standard prefabricated one. However, the microwavable self-customized foot orthosis is more stable throughout 30 min running. These results show that the different characteristics of the materials of the foot orthoses (composition, stiffness, hardness and thickness of the layers) could have a greater weight on impact accelerations than a better customization.

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Conflict of interest statement

The authors declare that there is no conflict of interest.

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Tables.

TABLE 1. Properties of the prefabricated foot orthoses tested in this study.

Standard foot orthoses (SFO)	Microwavable self-customized foot orthoses (MCFO)
	
• Composed of 100% polyurethane foam, Poron inserts in the heel and forefoot, and 100% polyester lining. • Thickness: 6 mm in heel and arch, and 5 mm in forefoot. • Hardness (° Shore A): 20-30° in heel and forefoot inserts, and 25° in arch. • About 40 g of mass approx.	• Composed formed by three layers: a bottom layer composed of polyurethane foam with nylon fabric, an intermediate layer composed of nonwoven polyester fabric with thermoplastic resins (thermoformable layer), and a top layer composed of fabric woven plus polyurethane foam with carbon and recycled. • Thickness: 6 mm in heel, 10 mm in arch and 3 mm in forefoot. • Hardness (° Shore A): 60° in heel, 45° in arch and 40° in forefoot. • About 75 g of mass approx.

Figure captions.

FIGURE 1. Mean (95%CI) of impact accelerations in different foot orthoses conditions: standard (SFO) vs. microwavable self-customized (MCFO). Significant difference between foot orthoses conditions for the matching min: $*P<.05$, $**P<.01$, $***P<.001$. Significantly different compared to the min indicated: $^{\gamma}P<.05$, $^{\gamma\gamma}P<.01$.

FIGURE 2. Mean (95%CI) of the shock attenuation in different foot orthoses conditions: standard (SFO) vs. microwavable self-customized (MCFO). Significant difference between foot orthoses conditions for the matching min: $*P<.05$. Significantly different compared to the min indicated: $^{\gamma}P<.05$.