Original Research

Assessment of a New Lateral Cushioned Casting Orthosis

Effects on Peroneus Longus Muscle Electromyographic Activity During Running

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Background: Classical medial wedge (CMW) orthoses have been prescribed to treat overpronation foot pathologies in runners. The effects of a novel supination orthosis (NSO) on the surface electromyography (EMG) activity of the peroneus longus (PL) muscle during a complete cycle of running have yet to be tested.

Purpose/Hypothesis: The purpose of this study was to compare the EMG activity of the PL in participants wearing CMW orthoses and NSOs versus neutral running shoes (NRS) during a full cycle of running gait. It was hypothesized that the PL muscle activity would be lower for the NSO compared with CMW or NRS.

Study Design: Controlled laboratory study.

Methods: Included were 31 healthy recreational runners of both sexes (14 male and 17 female; mean age, 38.58 ± 4.02 years) with a neutral Foot Posture Index and standard rearfoot-strike pattern. Participants ran on a treadmill at 9 km/h while wearing NSO (3-, 6-, and 9-mm thicknesses), CMW (3-, 6-, and 9-mm thicknesses), and NRS, for a total of 7 different conditions randomly selected, while the EMG signal activity of the PL was recorded for 30 seconds. Each trial was recorded 3 times, and the intraclass correlation coefficient (ICC) to test reliability of the measurements was calculated. The Wilcoxon pair to pair nonparametric test with Bonferroni correction was performed to analyze differences among the conditions.

Results: The reliability of all assessments was almost perfect (ICC, >0.81). For both the CMW and NSO, regardless of thickness, the PL activity was statistically significantly lower compared with the NRS ($P < .05$ for all). For all CMW thicknesses, the PL activity was lower compared with the respective NSO thicknesses, with the 3-mm thickness having the largest difference (CMW_{3mm}, 18.63 ± 4.64 vs NSO_{3mm}, 20.78 ± 4.99 mV; $P < .001$).

Conclusion: Both CMW and NSO produced reduced EMG activity of the PL muscle; therefore, they can be prescribed to treat overpronation pathologies without associated PL strain concerns. In addition, the NSO saved the enhancement material placed on the medial-rear side of CMW, making it easier to wear sports shoes.

Clinical Relevance: Knowing the safety of CMW and NSO will aid in understanding treatments for overpronation pathologies.

Keywords: orthosis; peroneus longus; supination; surface electromyography

During running activity, the neuromuscular coactivation of the different muscles of the lower limb plays an important part in achieving maximal strength to perform the exercise efficiently and to prevent injuries.[38] A malalignment of this equilibrium could cause alterations in either the foot or locomotor apparatus.[26] Foot overpronation has been identified as one of the most important factors of overuse of the lower limb during running,[19,20] and the prescription of foot orthoses is accepted as a valid tool to prevent and treat this condition and other medialized foot pathologies.[4]

Foot orthoses are often designed using enhancement material on the medial side, such as a medial heel skive[15] or classical medial wedge (CMW),[31,37] or an inverted orthosis.[3] The goal is to stop the total amount of the overpronation moment, to decrease the medial acceleration of the foot

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during the initial-contact and full-contact phases of gait,[18] or even to correct a valgus heel.[13] However, the lower limbs can be affected by kinetic and kinematic reactions to foot orthoses, for example, by changing the pulling activity of the muscles.[25] The use of traditional foot orthoses could affect the lever arm of the leg muscles and therefore affect ankle balance.[26]

Ankle instability is described as the condition of the foot moving away from the normal range of motion.[6] The peroneus muscles, involved in lateral ankle control movements, have been shown to be affected by supination moments of the hindfoot caused by classical orthoses,[42] and foot orthoses have led to increased muscle activity of the peroneus longus (PL) as measured using electromyography (EMG).[22,24,28]

To reduce the strain on the PL, we have developed a novel supination orthosis (NSO) with no medial enhancement material and with a lateral cushioned casting. The purpose of the present study was to compare the EMG effects of 2 kinds of orthoses on PL activity, a CMW and an NSO, with respect to a nonorthotic condition (neutral running shoes [NRS]) during a running test performed on a treadmill. It was hypothesized that the NSO would decrease PL activity more than the CMW or NRS would during running gait.

METHODS

The study protocol was approved by the institutional review board at Hospital Universitario Nuestra Señora de Valme, and the study was conducted according to the guidelines of the Declaration of Helsinki; all participants provided informed consent before the start of the study. The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology)[41] criteria and randomly consecutive examination techniques were followed to perform the present research.

Participants

All participants were recruited from a biomechanical clinic in Madrid, Spain, over a 3-month period (between September and November 2020). The following inclusion criteria were used to choose the participants: (1) healthy participants between 18 and 30 years of age, (2) recreational runners with a rearfoot-strike pattern who had been training for 3 to 4 hours per week for at least the past year, (3) neutral Foot Posture Index (FPI) (ie, values between 0 and +5 points[27]), and no lower limb injuries for at least 1 year before study enrollment. The exclusion criteria were (1) any pain during the test, (2) any drug use at the time of the assessments, and (3) not having joint mobility on the feet and lower limbs to allow for typical biomechanical behavior.[31,32] Body mass index (BMI) was taken into account to select a homogeneous sample in order to avoid hypothetical influences on the obtained results.

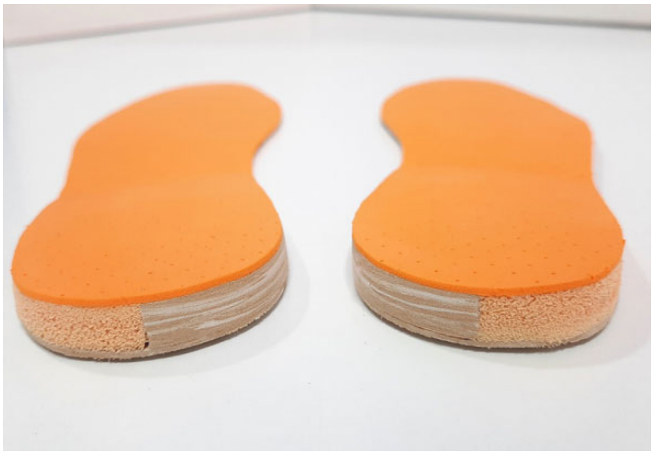

Figure 1. Novel supination orthosis made using 3 mm–thick ethylene-vinyl acetate and lateral cushioning casting filled with Poron.

Materials

The NSOs and CMWs used in the current study were custom-made in an external orthopaedics laboratory that was blinded to the present research. The NSOs were made from a flat sheet of ethylene-vinyl acetate (EVA) of high hardness. Three versions with different EVA thicknesses were created: 3 mm (NSO_{3mm}), 6 mm (NSO_{6mm}), and 9 mm (NSO_{9mm}). In all versions, a lateral cushioning casting was placed from the bisectrix of the rear part of the orthosis to its lateral edge, which was filled with viscoelastic rubber of Poron (Microban).[40] Finally, a low-hardness layer of EVA, 1 mm thick, was used to cover the upper layer of the orthosis (Figure 1).

The CMW was made using a flat sheet of EVA of high hardness and 1-mm thickness, with posting wedges made of EVA on the medial and rear sides. We created 3 versions

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Ethical approval for this study was obtained from Hospital Universitario Nuestra Señora de Valme (certificate No. 2115-N-20).

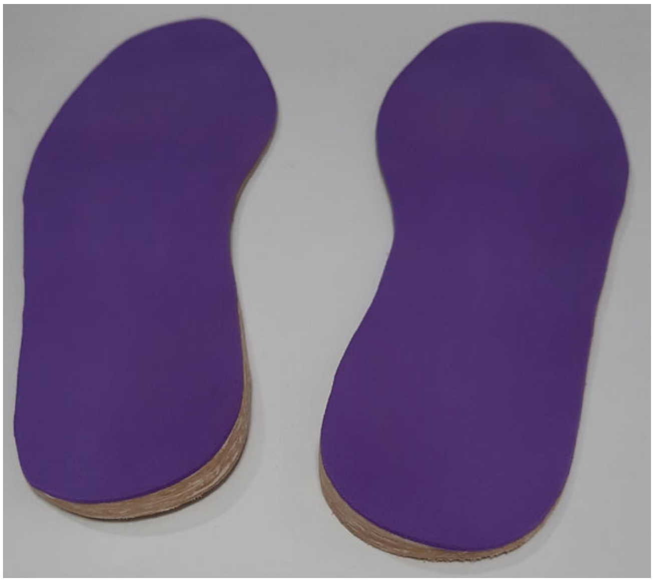

Figure 2. Classical medial wedge orthosis with 3 mm–thick medial ethylene-vinyl acetate enhancement on the rear side.

with different EVA thicknesses for the medial wedge posting: 3 mm (CMW_{3mm}), 6 mm (CMW_{6mm}), and 9 mm (CMW_{9mm}) (Figure 2).

To avoid other alterations to the normal foot biomechanical behavior, no further orthotic modifications were added. For both the NSOs and CMWs, the right and left feet had the same described characteristics. The NRS used in the study were Newfeel PW 100 M medium gray (model No. 2018022).

Instruments and Assessments

The NeuroTrac Simplex Plus (Verity Medical Ltd) EMG device with USB Bluetooth[33] was used to study the superficial EMG activity of the PL during running trials; 0.2 to 2000 mV was the range of record of the device, with a sensitivity of 0.1-mV root mean square, 10 m of free wireless (Bluetooth) connection range, and an accuracy of 4% of the reading from ±0.3 mV to 200 Hz, with a bandpass filter of 18 ± 4 Hz to 370 Hz ± 10% for readings <235 mV. The assessment of the signals was done via self-adhesive circular surface electrodes of 30-mm diameter made on high-quality hydrogel and conductive carbon film to detect the electrical action of the muscle fibers. The signal from each electrode was captured by the receiver module and filtered automatically via the NeuroTrac software (Verity Medical Ltd). It was sent via a unidirectional radioelectric secure connection to a computer, which digitally transformed it to generate the activity pattern data of each electrode.

An experienced podiatric clinician and researcher (R.S.G.) took the assessments of the participants. In order to localize the muscle belly and set the correct place of location of the sensors, he requested that each participant perform a foot eversion movement of the tested leg against clinician resistance for a few seconds; then, surface electrodes were placed on the most prominent bulge of the PL muscle, according to the European Recommendations for Surface EMG.[11] After that, maximal eversion force against hand resistance of the clinician was applied for 5 seconds to set the maximal voluntary isometric contraction needed to calibrate the device and normalize EMG data amplitudes of each trial.

Running Test

A motorized treadmill (Domyos T520) was used for the running test. Participants performed a trial run for 3 minutes at 5.7 km/h to become acclimatized to the treadmill[34] and to minimize external variables (eg, different floor slopes or running speeds). Then, the running test was performed at 9 km/h[36] under each of the 7 conditions (NRS, NSO_{3mm}, NSO_{6mm}, NSO_{9mm}, CMW_{3mm}, CMW_{6mm}, and CMW_{9mm}), randomly performed on the same day. The mean EMG peroneus muscle activity pattern of the right leg was recorded 3 times (ie, a total of 21 trials per participant) for 30 seconds each, leaving 5 minutes of rest between each test.[9] To avoid a possible imbalance of the musculoskeletal system, the same conditions for each trial were performed on the contralateral foot.

Statistical Analysis

To assess the reliability of the present study, the within-day trial-to-trial intraclass correlation coefficient (ICC) and standard error of measurement (SEM) were calculated for all participants under the 7 running conditions.[35] The ICCs were interpreted according to Landis and Koch[16] (<0.20, slight; 0.20-0.40, fair; 0.41-0.60, moderate; 0.61-0.80, substantial; 0.81-1.00, almost perfect agreement). To reach enough scientific validity, we considered ICCs >0.81 to be appropriate to support the present study. The SEM was calculated to assess the minimum detectable change (MDC) for all measurements. The Shapiro-Wilk test was used to assess the normality of the sample, with normal distribution considered $P > .05$. Participant variables were reported as means and standard deviations.

The nonparametric paired Friedman test was used to verify differences between conditions, and the Wilcoxon pair to pair nonparametric test with Bonferroni correction was performed to analyze differences between the conditions. Statistically significant differences were indicated when $P < .05$.

Sample size estimations to carry out the present study were assessed by the statistics unit at the Complutense University of Madrid, which used SPSS Version19.0 (IBM Corp) software to compare the EMG changes in PL activity during running among the 7 different study conditions. Data on the gastrocnemius lateralis in a previous study[34] showed a mean EMG value of 25.96 ± 4.68 mV for a novel orthosis compared with 22.27 ± 2.51 mV ($P < .05$) for typical running shoes. Considering a statistical power of 80%, $\beta = 20\%$, a 95% confidence interval, and $\alpha = .05$, a total of 30 participants were needed to perform this study.

TABLE 1
Participant Characteristics (N = 31)[a]

Characteristic	Value
Age, y	38.58 ± 4.02 (28.26-41.09)
Sex, male/female, n	14/17
Weight, kg	63.71 ± 9.79 (60.25-67.16)
Height, cm	168.87 ± 7.21 (166.32-171.41)
BMI	22.95 ± 2.38 (22.11-23.78)
FPI score	3.71 ± 0.19 (2.01-3.01)

[a]Data are reported as mean ± SD (95% CI) unless otherwise indicated. BMI, body mass index; FPI, Foot Posture Index.

TABLE 2
Reliability of EMG Measurements[a]

Variable	Value
NRS	
ICC (95% CI)	0.995 (0.992-0.998)
SEM, mV	0.455
MDC, mV	1.262
CMW_{3mm}	
ICC (95% CI)	0.988 (0.978-0.994)
SEM	0.515
MDC	1.426
CMW_{6mm}	
ICC (95% CI)	0.993 (0.986-0.996)
SEM	0.389
MDC	1.078
CMW_{9mm}	
ICC (95% CI)	0.996 (0.992-0.998)
SEM	0.318
MDC	0.881
NSO_{3mm}	
ICC (95% CI)	0.979 (0.962-0.989)
SEM	0.735
MDC	2.03
NSO_{6mm}	
ICC (95% CI)	0.981 (0.965-0.99)
SEM	0.75
MDC	2.09
NSO_{9mm}	
ICC (95% CI)	0.993 (0.988-0.997)
SEM	0.337
MDC	0.935

[a]CMW, classical medial wedging; ICC, intraclass correlation coefficient; MDC, minimum detectable change; NRS, neutral running shoes; NSO, novel supination orthosis; SEM, standard error of measurement.

RESULTS

The Shapiro-Wilk test showed a nonnormal distribution of the sample, and the Friedman test showed that values were different among the conditions. Of 51 participants initially assessed for eligibility, 16 participants did not meet the inclusion criteria, leading to 31 participants (14 male and 17 female) being ultimately enrolled in the study. The characteristics of the participants are shown in Table 1.

The reliability of the EMG muscle data during the 7 running conditions is shown in Table 2. ICCs for all recollected data were >0.81, indicating that the values had almost perfect reliability.[16] The SEM and MDC data also showed excellent reliability.

The mean EMG activity of the PL during the 7 running conditions is shown in Table 3. All EMG values for CMW and NSO underwent a statistically significant reduction with respect to NRS (23.08 ± 6.67 mV): CMW_{3mm}, 18.63 ± 4.64 mV ($P < .001$); CMW_{6mm}, 18.462 ± 4.5 mV ($P < .001$); CMW_{9mm}, 18.78 ± 4.74 mV ($P < .001$); NSO_{3mm}, 20.78 ± 4.99 mV ($P < .05$); NSO_{6mm}, 19.844 ± 5.34 mV ($P < .001$); and NSO_{9mm}, 19.55 ± 4.14 mV ($P < .001$). When comparing the 2 orthoses, significant differences were seen across all 3 thicknesses: CMW_{3mm}, 18.63 ± 4.64 versus NSO_{3mm}, 20.78 ± 4.99 mV ($P < .001$); CMW_{6mm}, 18.462 ± 4.5 versus NSO_{6mm}, 19.844 ± 5.34 mV ($P < .05$); and CMW_{9mm}, 18.78 ± 4.74 versus NSO_{9mm}, 19.55 ± 4.14 mV ($P < .05$).

DISCUSSION

The purpose of the present study was to assess the effects of NSO with a special supination design on mean PL muscle activity during a full running cycle in comparison with NRS and CMW. The EMG values for both CMW and NSO were lower than those for NRS during the running test. The wide variability among related studies in sample size and type (eg, poor participant recruitment[8,15,30] or participants with pathology[8,31-33] vs healthy[1,17] participants) and experimental conditions (eg, walking[8,30,31,34-36] vs running[2,14,21] and intramuscular electrode[32,34] vs surface electrode[2,17,22,39] assessments of PL activity) renders any meaningful comparison between results difficult.

According to our results, PL muscle activity for both CMW and NSO values decreased with respect to that of the NRS. These surprising results are in agreement with the findings of other authors, who detected a decrease in PL muscle activity with a similar supination element to that used in our study, pronation-control sports shoes during running[30]; this could suggest that the tendinous portion of the PL muscle could undertake the mechanical responsibility of excess supination caused by CMW and NSO, as a passive tissue structure, allowing the muscle to not show any change in its electric signal pattern (Figure 3). In addition, the muscle belly of the PL is far from the force application point, which is placed on the medial rearfoot, and the longitudinal strain to the PL caused by CMW or NSO could be assumed by its own tendon before affecting the muscle belly.

On the other hand, the medial arch support present in sports shoes of previous study[30] could also discharge PL activity because the structure sustains the fibers of the muscle that cross beneath the midfoot, which inserts on the base of the first metatarsal bone and therefore could prevent plantarflexion. For some authors, the increasing activity has been detected only during the preactivation phase using a foot orthosis compared with control status[2]; in contrast to our results, this is likely due to the assessment of each phase of running gait, whereas we recorded the full

TABLE 3
Comparison of EMG Signal Amplitudes of the Mean Peroneus Longus Muscle Activity Between Different Study Situations[a]

	EMG Activity, mV[b]	*P* (vs NRS)	*P* (Within Orthotic Group)	*P* (Across Groups)
NRS	23.08 ± 6.67 (20.63-25.53)	—	—	—
CMW$_{3mm}$	18.63 ± 4.64 (16.93-20.34)[c]	<.001[c]	—	—
CMW$_{6mm}$	18.46 ± 4.5 (16.8-20.12)[c]	<.001[c]	.481 vs CMW$_{3mm}$	—
CMW$_{9mm}$	18.78 ± 4.74 (17.05-20.53)[c]	<.001[c]	.875 vs CMW$_{3mm}$ .799 vs CMW$_{6mm}$	—
NSO$_{3mm}$	20.78 ± 4.99 (18.95-22.61)	<.05[d]	—	<.001[c] vs CMW$_{3mm}$
NSO$_{6mm}$	19.84 ± 5.34 (17.88-21.08)	<.001[c]	<.05[d] vs NSO$_{3mm}$	<.05[d] vs CMW$_{6mm}$
NSO$_{9mm}$	19.55 ± 4.14 (18.03-21.07)	<.001[c]	<.05[d] vs NSO$_{3mm}$ .430 vs NSO$_{6mm}$	<.05[d] vs CMW$_{9mm}$

[a]CMW, classical medial wedge; mm, millimeters; NRS, neutral running shoes; NSO, novel supination orthosis. Dashes indicate not applicable.
[b]Data are presented as mean ± SD (95% CI).
[c]Statistically significant difference ($P < .001$).
[d]Statistically significant difference ($P < .05$).

Figure 3. Schematic model showing the effect of the study orthoses. Dashed lines indicate the Helbing axis. (A) Right rearfoot without any orthosis. (B) Classical medial wedge orthosis (red shading) with medial enhancement made of ethylene-vinyl acetate on the medial-rear side. The red arrow shows the "uplift" effect of the enhancement on the right foot, the curved black double arrowhead shows the strain of the tendon portion of the peroneus longus (PL) muscle, and the curved arrow shows the supination effect of the orthosis. (C) Novel supination orthosis (red shading) with lateral cushioning casting filled with Poron (white portion). The small red arrows show the Poron depressed by the weight of the participant, the large red arrow shows the lateral "drop effect" of the right foot, the black double arrowhead shows the strain of the tendon portion of the PL muscle, and the curved arrow shows the supination effect of the orthosis.

cycle or running gait with total amount of EMG activity. In addition, this is the first study reporting isolated supination orthosis effects, without any interference piece effect (eg, medial longitudinal arch[2,21,22] or custom orthosis[2,21]) that could infer some load under the navicular bone or first ray and promote some changes on PL activity, providing benefits in the midstance and push-off phases when the Windlass mechanism is activated.[7,12]

Moreover, increasing rearfoot supination moments via medial wedging in runners with overpronation foot pathology[21] may increase the amount of the lateral ground-reaction force and thus increase PL EMG activity to dampen leg impact vibrations. Studies have shown no changes during walking,[1,39] just as our results comparing CMWs between themselves during running. However, some authors have found higher PL muscle activity during walking: Murley and Bird[22] and Murley et al[23] tested foot orthoses on pronated and flat feet and found higher EMG activity on the PL, but the current spasticity of PL in pes planus foot is known[10]; therefore, it is likely that antipronation orthoses could promote more tightness on PL muscle fibers and enhanced signal values. In addition, it is important to take into account that the amplitude of an EMG signal between healthy participants and those with pathology could change due to there being less recruitment of the fast and slow tired fibers of the muscle motor units.[5]

Ludwig et al[17] also recorded an increase in PL muscle activity during walking gait; however, their participants were wearing a special orthosis with a peroneal pressure point, and they argued that this had a direct influence on the sensitivity of the foot receptors and the neuromuscular response of the PL.

According to our results, there was a statistically significant decrease in PL activity when comparing CMW versus NRS and NSO versus NRS, which was more pronounced when wearing CMW; therefore, it is presumable to think that either elevated element on the rearfoot can produce a saving muscle activity during the push-off phase that gives an advantage to the lateral-rear muscle groups, comparable to the Windlass mechanism assumption.[8,12] The total amount of the decreases reported in the present work was larger when wearing CMW than NSO perhaps because of the more powerful effect of hard CMW on PL tendon strain and its muscle belly relief than that obtained via cushioning NSO. As has been reported previously with running shoes[29] and novel orthoses,[34] it seems that wearing cushioning (vs hard materials) may induce more muscle activity in order to balance the foot during running gait.

NSO and CMW showed almost identical values for PL EMG responses; however, the NSO took less space than the CMW in shoes because it was made using lateral rearfoot casting and refilling with Poron while the CMW was made using medial enhancement. Thus, NSO can be prescribed under the same recommendations of CMW, reaching almost the same EMG benefits.

Limitations

The EMG device has high sensitivity, and the maximal voluntary isometric contraction test used to calibrate the signal device can vary among participants. These circumstances must be considered when interpreting the findings of the present study.

Because of the deep location of the peroneus brevis muscle belly and how difficult it is to reach its muscle activity via the superficial EMG device used in the present study, we decided to rule out the assessment of this muscle.

Future studies are required to know how many supination moments the tendinous portion of the PL is able to bear before its motor units are recruited to express a detectable EMG signal. In addition, future assessment will be required to establish the different loading patterns wearing cushioning NSO versus CMW, highlighting changes on pressure points of the lateral side of the rearfoot. Tibialis posterior muscle and Achilles tendon activity will also have to be investigated using NSO because of its great involvement on rearfoot biomechanics of gait. The MDC values were lower than the ±mV difference obtained between NRS vs CMW or NRS vs NSO. In addition, considering that the accurancy set for the device was around 4%—and considering that SEM values obtained in the study were around or under this 4%—these results are considered to be statistically valid.

CONCLUSION

Foot orthoses with medial corrections have been used to treat overpronation foot problems in runners. Moreover, NSOs have been designed to relieve the current CMW instability produced on the lateral muscles of the ankle. In the present study, it has been shown that PL EMG activity decreases when wearing either CMW or NSO versus NRS during a full cycle of running in healthy participants. Therefore, both can be prescribed to treat overpronation pathologies without associated PL strain precautions with the advantage that NSO can save the enhancement material placed on the medial-rear side of the CMW, making it easier to wear sports shoes. The prescription of both NSO and CMW decreases EMG activity, which has not been studied previously.

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