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Proprioceptive effects on gait and postural stability through mechanical stimulation with an Internal and External Heel Wedge: An interventional single-arm study

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ABSTRACT

Background: Previous studies have shown that the stimulation of the foot sole can provide important information about the body's position and locomotion. However, these studies do not clarify how the position of the mechanical stimulation on the foot sole affects the gait cycle.
Aims: This interventional single-arm study aims to verify if the insertion of an Internal Heel Wedge (IHW) and External Heel Wedge (EHW) can modify the stabilometric and podobarometric variables, the functional changes during the gait cycle, the different responses between the dominating lower limb and the non-dominating lower limb, and the potential temporal summations of the proprioceptive stimulation.
Method: Twenty-three healthy subjects (age 31 ± 5 years; weight 62 ± 1 kg; height 168±6 cm), with a right dominating lower limb, were recruited. The IHW and EHW were created out of half-moon-shaped cork pieces having a 1.5 mm thickness, 6 cm length and 3 cm height. The sequence of tests foresaw trials without IHW or EHW (Baseline), trials with IHW or EHW (Acute), trials after an adaptation period of 15 min on a treadmill with IHW or EHW (after 15').
Results: Data showed statistically significant variations in the Step Rate, Duration of the cycle of the left step and Single Right Support phase for the IHW, Duration Single Right support and Single Left Support phase for the EHW.
Conclusion: Data showed that a thin proprioceptive stimulation of the plantar arch was enough to induce changes in the gait cycle and that, upon changing the position of the proprioceptive stimulation, the functional response of the feet was inverted. These results can help health professionals provide a correct interpretation of the clinical data during follow-ups, avoiding undesirable and harmful effects on the patients' recovery.

1. Introduction

The body posture is a complex system and its different organizational models are the effects of the interaction of several postural receptors amongst the feet, which perform a key function.

Several studies have demonstrated that different kinds of stimulations of the foot sole can produce postural changes and provide important information about the body's position and locomotion.

These phenomena occur thanks to the take-over of the three spatial components of the ground reaction during foot support, by means of the mechanoreceptors of the feet. In fact, the cutaneous plantar receptors do not measure sway, but are related to different parameters of the ground reaction force f, such as the vertical component f_V and the horizontal, or shear, component of the force f_H (Morasso and Schieppati, 1999).

Seventy percent of the foot mechanoreceptors are of a fast-adapting type, distributed randomly on the plantar surface. In particular, 104 cutaneous mechanoreceptors were found in the foot sole, of which 15 were of the slow-adapting type I (14%); 16 of the slow-adapting type II (15%); 59 of the fast-adapting type I (57%); and 14 of the fast-adapting type II units (14%). The activity of these receptors was evaluated with tungsten microelectrodes inserted

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through the popliteal fossa and into the tibial nerve. Researchers observed that they did not produce any electrical background activity in the absence of foot support; however, by stretching the skin of the foot sole in the heel region, the receptors located in this area produced a number of potential actions proportional to the stretching of the skin (Kennedy and Inglis, 2002). Furthermore, the same authors indicated that the receptive field-distribution of cutaneous mechanoreceptors in the heel sole is mostly characterised by the fast-adapting type I receptors in the internal part of the heel, and by the slow-adapting type I receptors in the rear part of the fifth metatarsal bone.

Kavounoudias et al. (1998) showed that the cutaneous afferent information, which originates from the main supporting areas of the feet, has sufficient spatial relevance to inform the CNS about body position. In fact, the study has demonstrated that the direction of the sway of the body depends on the stimulated foot areas, and that this always originates from the side opposite to the one concerned by the increased pressure of the vibration-stimulation.

The sensory feedback from the feet plays an integral role in the modification of the motor patterns that govern locomotion, and this fact suggests that the body can detect small biomechanical changes in the external environment and alter gait patterns as a defensive mechanism (Nurse and Nigg, 1999).

Furthermore, the compensations of postural reactions during gait are affected by podalic information (Perry et al., 2000), but consistent postural responses can be observed also in the standing position, using mechanical stimulations on the plantar arch (Maurer et al., 2001).

Gordon et al. (1995a, b), suggest that the podalic stimulation can restructure functional relationships between the lower limbs and the trunk.

However, the proprioceptive insoles do not seem to have any influence on a pathological condition. Noll. et al. (2017) have studied the influence of proprioceptive insoles on idiopathic scoliosis in patients with Cobb's angle between 10° and 20°, and have not observed significant variations on Cobb's angle after an 8-week use of the insoles.

According to current scientific literature, only a small number of authors have studied the influence of a thin mechanical stimulation applied to the plantar arch with a 3 mm thickness (Forth and Layne, 2007, 2008; Janin and Dupui, 2009; Foisy et al., 2015), but none have as of yet investigated any changes in the functional relationships of the gait cycle and postural stability using a thicknesses inferior to 3 mm.

This interventional single-arm study aimed to evaluate changes in the gait cycle, modifications of stabilometric and podobarometric variables, and different responses between the dominating lower limb and non-dominating lower limb, by means of a mechanical stimulation with a 1.5 mm thickness, such as the Internal Heel Wedge and the External Heel Wedge. We hypothesized that a thin mechanical stimulation, placed on the plantar arch, was enough to produce functional changes during the gait cycle and improve postural stability thanks to the proprioceptive effects on the foot sole, without altering the anatomical conditions of the lower limbs.

2. Methods

2.1. Participants

This study was conducted at the Adapted Training and Performance-Research group Laboratory (SUISM, University of Turin). All the participants were selected through a verbal invitation presented to the students of the Faculty of Motor and Sports Sciences. A researcher, involved in the study, informed the students about the project during an interview. After acceptance by the participants, the same researcher assessed their eligibility in a second interview, taking into account the exclusion and inclusion criteria established and described below.

Twenty-three healthy subjects with right dominating lower limbs were selected (age 31 ± 5 years; weight 62 ± 1 kg; height 168±6 cm; male: 11, female: 12; Table 1). The exclusion criteria were: left dominating lower limb, presence of dysmorphic features of the spine and lower limbs, recent fractures of the skeleton of the lower extremities, neurological diseases, recent muscular injuries, hip and knee prosthesis, leg length discrepancy. The inclusion criteria were: right dominating lower limb, age between 25 and 40 years. All of the participants were informed about the purpose of the study by signing an informed consent form before participation. This study was approved by the Ethics Committee of the University of Turin, protocol number 176863 and registered on the Australian New Zealand Clinical Trials Registry with registration number ACTRN12619001759189.

2.2. Equipment

Stabilometric and podobarometric analyses were performed using the P-Walk (BTS S.p.A, Garbagnate Milanese, Italy): the subjects were positioned barefoot on the podobarometric platform, with their feet placed at 30° (Allum et al., 1998), arms relaxed along their sides, eyes open and directed towards a target placed in front of them at eye level, at a distance of 2m. The feet were positioned with the second toe and the centreline of the calcaneus on the same reference line. The trials were conducted for 30 s with open eyes.

Gait Cycle analysis was performed using the G-Walk (BTS S.p.A., Garbagnate Milanese, Italy): the subjects walked with their shoes on for 5 m, with a triaxial accelerometer positioned in the space between the sacrum bone and the fifth lumbar vertebra.

The period of adaptation was performed using the Pro-Form PF 500CX (ICON Health & Fitness Inc., Utah, USA): the subjects walked on the treadmill for 15 min at the speed of 4 km/h, at a 0° inclination.

The mechanical stimulation used on the plantar arch was created with half-moon-shaped cork pieces, having a 1.5 mm thickness, 6 cm length and 3 cm height. A line was drawn on the half-moon, 2 cm from the corner that identified the rear part of the stimulation (Fig. 1).

2.3. Study design

The Ball-Kick Test was applied to identify the dominating leg. In this test, the subjects were asked to kick a ball with moderate intensity and maximum accuracy. The leg used to kick the ball was identified as the dominant leg (Hoffman et al., 1998).

The Internal Heel Wedges (IHW) were inserted on both feet in correspondence with the abductor hallucis muscle. During this process, the researcher used his other hand to identify the insertion of the abductor hallucis muscle. Subsequently, the researcher drew a vertical line from the insertion point (Fig. 2).

The External Heel Wedges (EHW) were inserted on both feet in correspondence with the abductor digiti minimi muscle. In order to insert the mechanical stimulation on the muscular body of

Table 1
Demographic characteristics of the sample.

	N Subjects	Age	Weight	Height	Gender
Sample	23	31 ± 5 years	62 ± 1 kg	168±6 cm	male: 11 female: 12

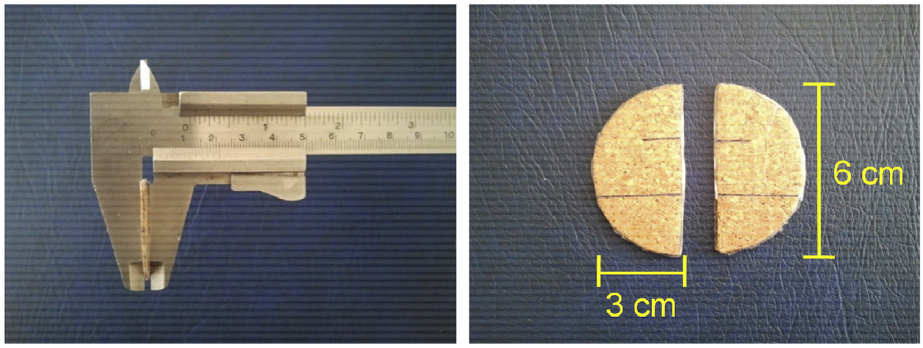

Fig. 1. Mechanical stimulation on the plantar arch.

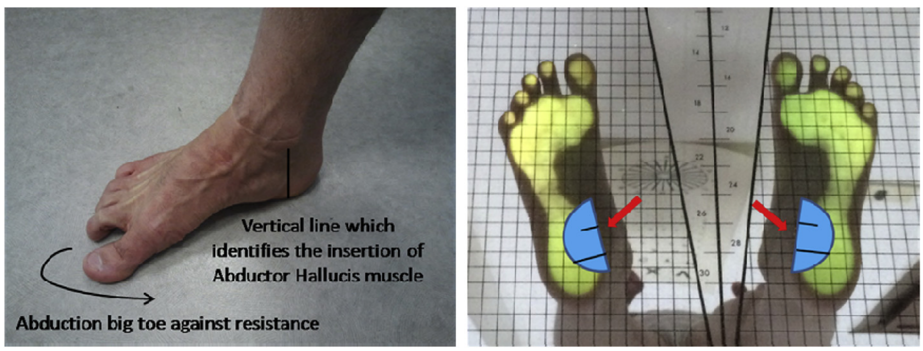

Fig. 2. Insertion procedure of the Internal Heel Wedge (IHW).

abductor hallucis muscle, the subjects were placed in an upright position, and the researcher drew a vertical line from the summit of the lateral malleolus (Fig. 3).

In both cases, the line of the cork half-moon was then aligned with the vertical line drawn on the subject's heel.

The sequence of the trials on the P-Walk, the G-Walk and on the treadmill was designed to retain the same experimental conditions. In this way, the subjects carried out the trials on the first two devices without the use of the IHW or EHW (Baseline); immediately after they repeated the same measurement with the insertion of the IHW or EHW (Acute). Following a period of adaptation on the treadmill, the subjects repeated the trials on the P-Walk and on the G-Walk, retaining the IHW or EHW (After 15').

The period of adaptation to the mechanical stimulation was performed on the treadmill, where the subjects walked for 15 min at the speed of 4 km/h and a 0° inclination, with the insertion of IHW or EHW inside the shoes. Only one group of twenty-three subjects was tested and all the participants wore the same mechanical stimulation. The participants were unaware of the applied procedure and performed the sequence of trials with the IHW, which was then repeated after one week with the EHW. The researchers were not blinded because it was necessary to engage operators with experience to carry out the mechanical stimulation insertion procedure correctly (Single Blind Study). Table 2 summarize all the phases of the study.

2.4. Statistical analysis

The Parametrical statistical analysis was used (Repeated Measures ANOVA; Post-Hoc Tukey's Multiple Comparison Test) after performing the Shapiro-Wilk normality test for weight, height, age and Step Rate, observing that all three variables passed the normality test. The data was processed using the GraphPad Prism 5 software (GraphPad Software, Inc., USA). The level of significance, "p" was fixed to < 0.05. The Effect Size (ES) was calculated for the interpretation of the significance of variations, and read

Fig. 3. Insertion procedure of the External Heel Wedge (EHW).

Table 2
Sequence of study phases.

	Phases Of The Study								
	T0	T1	T2	T3	T4	T5	T6	T7	T8
Recruitment	x ——	x							
Eligibility Criteria		x ——	x						
Informed Consent			x						
Trials				x ——	x				
Data Collection						x ——	x		
Statistical Analysis								x ——	x

T0 – T1: 2 week; T1 – T2: 1 week; T3 – T4: 1 month; T5 – T6: 1 week; T7 – T8: 1 week.

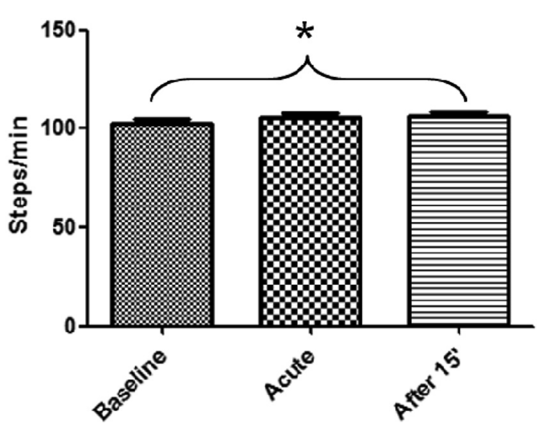

Fig. 4. Step Rate: significant differences, with *P < .05.

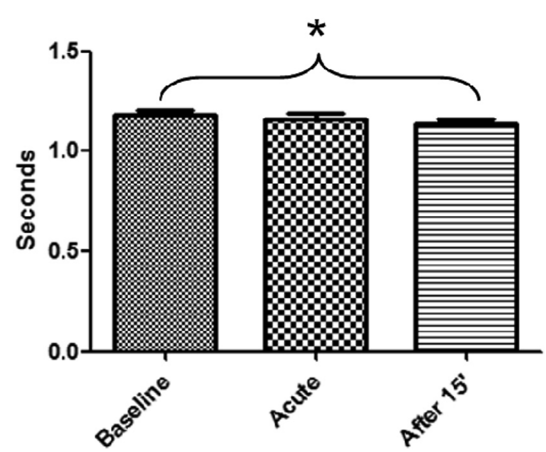

Fig. 5. Duration of the cycle of the left step: significant differences, with *P < .05.

accordingly: 0.01 very small; 0.20 small; 0.50 medium; 0.80 large; 1.20 very large; 2.0 huge (Cohen, 1992; Sawilowsky, 2009). The Post-Hoc power analyses were calculated using G*Power (Version 3.1.9.4, Germany) (Faul et al., 2007).

3. Results

3.1. Internal Heel Wedge (IHW)

We observed significant statistical variations in:

- Step Rate (p: 0.0316; Post-Hoc Baseline vs. After 15'; ES: 0.36; Power test: 0.96. Fig. 4);
- Duration of the cycle of the left step (p: 0.0421; Post-Hoc Baseline vs. After 15'; ES: 0.01; Power test: 0.05. Fig. 5);
- Single Right Support phase (p: 0.0051; Post-Hoc Baseline vs. After 15'; ES: 1.02; Power test: 0.99. Fig. 6).

3.2. External Heel Wedge (EHW)

We observed significant statistical variations in:

- Duration Single Right support (p: 0.0391; Post-Hoc Baseline vs. After 15'; ES: 0.64; Power test: 0.99. Fig. 7);
- Single Left Support phase (p: 0.0003; Post-Hoc Baseline vs. After 15'; ES: 0.93; Power test: 0.99. Fig. 8).

Table 3 shows the details of the significant variables with the IHW and EHW indicating mean, standard deviation, p—values, effect size, power test and Post-Hoc of the different testing conditions.

We did not observe changes in the P-Walk and in the "Symmetry Index of the tilt, lateral inclination, and rotation of the pelvis" variables of the G-Walk with the IHW or EHW (Table 4).

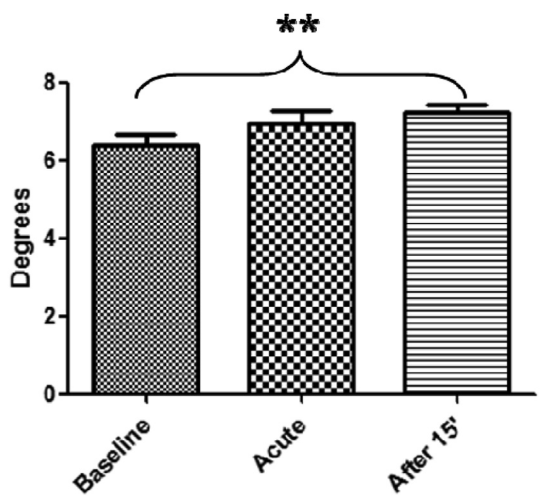

Fig. 6. Single Right Support phase: significant differences, with *P < .05.

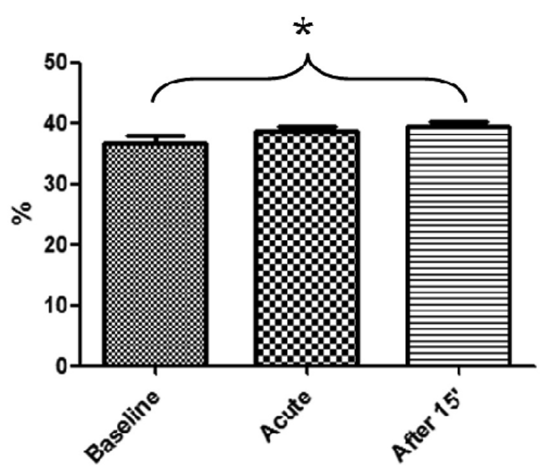

Fig. 7. Duration Single Right support: significant differences, with *P < .05.

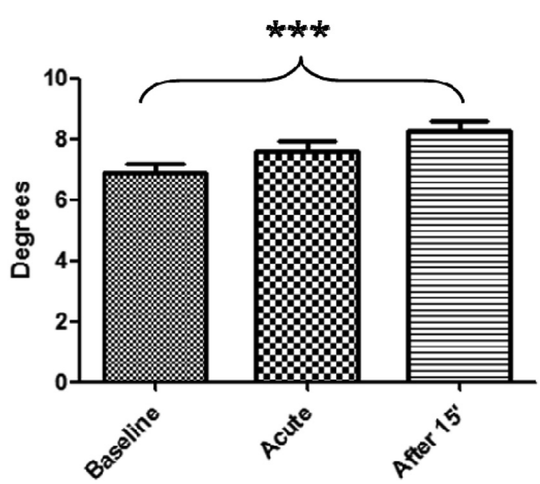

Fig. 8. Single Left Support phase: significant differences, with *P < .05.

4. Discussion

This research aimed to understand whether a thin mechanical stimulation placed on the plantar arch, such as an IHW or an EHW, could produce tangible functional changes in the postural stability and the gait cycle.

We found significant functional changes in the gait cycle but we did not observe changes in postural stability. This data is in consonance with Morasso et al. (1999) who suggest that the cutaneous plantar receptors do not measure sway, but are related to different parameters of the ground reaction force f, such as the vertical component f_V and the horizontal or shear component of the force f_H. The findings are also consistent with Roll et al. (2002), who suggest that the cutaneous afferent information, coming from the main supporting areas of the feet, have sufficient spatial relevance to inform the CNS about body position. Basing ourselves upon the aforementioned data, we have hypothesized that this kind of mechanical stimulation works on the mechanoreceptors of the foot, and not on the neuromuscular spindle, as indicated by classical posturology. The results obtained indicate that the EHW involves functional changes on the non-dominating lower limb of the selected test subjects (significant variation of “Single Left Support phase” variable). Furthermore, upon changing the position of the mechanical stimulation, i.e. from EHW to IHW, we observed that the podalic response was reversed on the single support phase parameter. This parameter is the angle of curvature of the support-time of the foot: the shorter the time of support of the foot, the greater the angle of curvature. This indicates that when the heel is stimulated with an IHW, the dominating foot, when engaged in the walking motion, reacts more rapidly than the non-dominating foot; however, the phenomenon is reversed using the EHW. It is interesting to observe that these two variables have the highest effect size and power test amongst all the significant variables (1.02 with IHW and 0.93 with EHW, both with power test of 0.99). This data is linked to the particular trend of the standard deviation in the three experimental conditions (Table 1): compared to the experimental condition defined “Baseline”, both with an IHW and with an EHW, the standard deviation tends to increase in the experimental condition defined “Acute” but subsequently decreases in the experimental condition defined “After 15'”. Furthermore, in this latter condition, the standard deviation displays values that are even lower than in the experimental “Baseline” condition. We have postulated that this trend of standard deviation could be related to the intrinsic adaptation features of the neuromuscular system after a mechanical stimulation: it is likely that a mechanical stimulation can produce an initial instability of the body posture and then effectively compensate after a period of adaptation. From a neurological point of view, this phenomenon can be explained by the predictive control during walking that is specifically modulated by the cerebellum. The cerebellum constantly regulates the output coming from the CPGs (Choi and Bastian, 2007) and is involved in the magnitude of behavioural adaptation and effects of the spatial characteristics of motor adaptation during the gait cycle (Jayaram et al. 2011, 2012). The use of mechanical stimulations under the foot is based on the concept of using the tactile feedback systems of the foot–brain connection (Aminian et al., 2013).

Despite the initial instability produced by the mechanical stimulation, no significant variables were observed on the P-Walk (Table 2): the CoP and the pressure distribution of the feet did not undergo significant changes. This phenomenon can be explained by the fact that any changes of the sway of the body in an upright position are quickly compensated by the vestibular system which, by using visual and somatosensory information, appears to have a greater sensitivity in terms of absoluteness of perception, because it always refers to gravity (Lopez et al., 2015). The cerebellum, on the other hand, seems most involved during gait initiation, anticipatory postural adjustments, and control of the locomotor programmes during their execution (Richard et al., 2017). Furthermore, these data are consistent with the results of the research by Tramontano

Table 3
Mean, standard deviation, p – values, effect size, power test and post – hoc of the different testing condition with the IHW and EHW.

Significant variables	Baseline		Acute		After 15 min.		P value (P < 0,05)	Effect size	Power test	Post - Hoc
	Mean	SD	Mean	SD	Mean	SD				
IHW										
Step rate (steps/min)	102,61	10,27	105,54	10,95	106,43	11,51	0,0316 (*)	0.36 (Small)	0.96	Bas. vs After 15′
Duration of the cycle of the left step (seconds)	1,18	0,12	1,16	0,14	1,14	0,12	0,0421 (*)	0.01 (Very Small)	0.05	Bas. vs After 15′
Single Right Support phase (degrees)	6,4	1,38	6,96	1,45	7,21	1,14	0,0051 (**)	1.02 (Large)	0.99	Bas. vs After 15′
EHW										
Duration Single Right support (%)	36,69	5,65	38,71	2,89	39,51	3,02	0,0391 (*)	0.64 (Medium)	0.99	Bas. vs After 15′
Single Left Support phase (degrees)	6,86	1,63	7,59	1,76	8,27	1,46	0,0003 (***)	0.93 (Large)	0.99	Bas. vs After 15′

Table 4
P value of the variables of the P – Walk and of the Symmetry Index of the G – Walk.

Variables	P value		Baseline vs Acute		Baseline vs After 15′		Acute vs After 15′	
	IHW	EHW	IHW	EHW	IHW	EHW	IHW	EHW
P-Walk								
CoP. Av. X	0,9969	0,627	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
CoP. Av. Y	0,4312	0,6882	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
St. Dev. X	0,0564	0,5506	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
St. Dev.Y	0,4102	0,2665	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
CoP. Dist.	0,967	0,4052	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Av. Speed	0,9353	0,4979	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Dist./Surf.	0,3124	0,4332	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Surf. Ell. Left Foot	0,1769	0,6584	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Surf. Ell. CoP	0,2045	0,3287	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Surf. Ell. Right Foot	0,5943	0,6195	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Distribution Angle	0,9676	0,3185	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Weight Distr. Left Foot	0,8518	0,6092	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Weight Distr. Right Foot	0,8537	0,3175	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
G-Walk								
S.I.[a] pelvis tilt	0,1265	0,6705	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
S.I.[a] pelvis lateral inclination	0,1918	0,4182	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
S.I.[a] pelvis rotation	0,5837	0,5624	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

[a] Symmetry Index.

et al. (2019), where the first effects of a podalic stimulation with a 3 mm thickness insole on the stabilometric platform with open eyes, were observed only after 7 days from the initial stimulation.

Following what happened in the Single Support Phase of the variable, the parameters of the duration of the gait cycle also underwent a reverse response, passing from the non-dominating lower limb, upon insertion of the IHW, to the dominating lower limb, after the insertion of the EHW. In fact, the results showed a significant variation of the Duration of the cycle of the left step (p: 0.0421; Post-Hoc Baseline vs. After 15′, ES: 0.01) and the Duration of the Single Right Support (p: 0.0391; Post-Hoc Baseline vs. After 15’, ES: 0.64), but only the last parameter showed a high power test (0.99). This result could be related to the fact that all the participants in the study had a right dominating lower limb, thus providing faster responses to mechanical stimulation than the left lower limb (this hypothesis could be confirmed through an additional study that would take into consideration participants with a left dominating lower limb). Therefore, when increasing the speed of the response of a lower limb (indicated by the variable Single Support phase), the other limb is forced to change the time parameters to maintain a normal gait cycle and, therefore, a Step Rate that falls within standard limits.

Another important parameter to be taken into consideration is the Symmetry Index of the pelvis' position on the three spatial planes: Table 2 shows that the "Symmetry index of the tilt, lateral inclination and rotation of the pelvis" of the G-Walk variables, are not significant. This indicates that a rise of 1.5 mm allows the production of functional changes in the gait cycle, without altering or stressing the joint structures, suggesting that this kind of mechanical stimulation affects the neuromuscular system, producing changes during walking, without altering the skeletal system. Finally, this data is connected with the variable defined "Step Rate" that appears significant with the use of the EHW. We can observe an increase in the number of steps throughout the three experimental conditions, probably caused by an increase in the Single Right Support phase, but the average remains within the standard limits indicated by the device (101.8–109.4). Moreover, this variable has a small effect size (0.36), whereby we cannot talk about an incidence of lameness. If we want to produce an effect on the skeletal system, we should probably have to apply a thicker mechanical stimulation.

All these findings are in consonance with Nurse et al. (2001, 1999) and Hatton et al. (2012), who showed that a mechanical stimulation on the plantar arch can produce changes in the gait parameters, and Chuckpaiwong et al. (2008), who suggested that the podalic stimulation can alter the biomechanics of the foot and vary the normal distribution of pressure during walking.

5. Study limitations

Though this study has highlighted the amount of time after which a mechanical stimulation of the plantar arch starts to produce its effects, and has further demonstrated that upon changing the position of the proprioceptive stimulation the functional response of the feet is inverted, we must recognise its limitations. Although the parametrical statistical analysis used in this study allows to identify significant changes within the same group between the "Baseline" condition (without the IHW or the EHW) and the "After 15'" condition (with the IHW or the EHW), the lack of a control group does not ensure that the data obtained are actually consequent to the use of this type of podalic stimulation. Our research does not quantify the duration of these functional changes, or if their effects will subside after removing the mechanical stimulation from the shoes. Furthermore, we do not know if this kind of mechanical stimulation can produce positional changes of the feet or of the lower limbs in general, since we observed only functional changes during the gait cycle. The key limitations in this study could be addressed in a future paper, with the purpose of clarifying the neuromuscular and postural aspects related to the use of thin mechanical stimulations on the plantar arch.

6. Clinical relevance

The clinical practice in the rehabilitative field that envisages the use of thin mechanical stimulations on the plantar arch, currently makes extensive use of insoles with a thickness between 3 and 1.5 mm. Little is known, however, on the inserts' actual effects and on the role played by the dominant side of the lower limbs.

This study, in addition to indicating how the thinnest mechanical stimulation used in clinical practice may already produce effects on the gait cycle, recognises that the dominant side of the lower limbs must be taken into account, because by changing the position of the proprioceptive stimulation, the functional response of the lower limbs is reversed. It is important to consider this fact during the postural and clinical analysis of the patient's symptoms and, primarily, during the designing and creation of the corrective insoles that apply this type of mechanical stimulation to the plantar arch. This information will aid operators in avoiding the incorrect positioning of the mechanical stimulation, which could produce undesired and harmful effects on the patient's recovery. Finally, the recognition of the incidence of functional changes that depend on the positioning of the proprioceptive stimulations can help health professionals provide a correct interpretation of the clinical data during follow-ups.

7. Conclusions

The experimental results of this study define that a 1.5 mm-thick proprioceptive stimulation on the plantar arch is enough to induce changes in the gait cycle. These changes occur after a 15-min time span, but the data is insufficient to confirm if they are able to produce tangible postural variations over a longer period of time.

Declaration of competing interest

None.

CRediT authorship contribution statement

Alessandria Marco: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Data curation, Writing - original draft, Writing - review & editing, Visualization, Supervision, Project administration. **Gollin Massimiliano:** Validation, Formal analysis, Resources, Writing - original draft, Supervision, Project administration.

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