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Pilot study demonstrating that sole mechanosensitivity can be affected by insole use

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ABSTRACT

Insoles are known to alter plantar loads and thus plantar sensory input. We therefore hypothesised that plantar somatosensory sensation could be modified over time by use of hard metatarsal pads. A sample of 12 healthy female participants was randomly allocated to either soft metatarsal pads ($n = 6$, latex foam, Shore A11) or hard metatarsal pads groups ($n = 6$, thermoplastic, ShoreA65). All wore the same shoe type and pedometers measured daily activities. Using a bespoke actuated device, multiple mechanical stimuli were applied to the forefoot and rearfoot before and after 8 and 30 days of wearing the pads. A control test comprised estimation of multiple auditory sensations at day 0, 8 and 30. Changes in detection of the mechanical and sound stimuli were estimated using the Stevens power function, $\Psi = k \times \Phi^n$ (estimate = Ψ; stimulus = Φ). The k coefficient measured the sensitivity, i.e. the lowest detectable load/sound, and the n coefficient the gain in perception over time.

After 30 days, hard metatarsal pads group had increased plantar sensitivity in the forefoot but not the rearfoot. The soft metatarsal pads group showed no changes in plantar sensitivity and the detection of auditory sensation remained stable over the 30 days.Metatarsal pads with relatively high hardness increased the perception of the lowest mechanical stimulus in the forefoot compared to soft metatarsal pads. This provides initial evidence of the potential for changes in plantar somatosensory sensation due to choice of orthotic designs in patients with foot-related problems.

1. Introduction

The sensitivity of the plantar surface has not been extensively explored despite the fact that it is the major weight bearing surface during gait and standing. A prior electrophysiological study [1] reported the presence of both slow (Merkel and Ruffini corpuscles) and fast (Meissner and Pacinian corpuscles) adapting receptors, with far greater numbers of the latter (71% of tested units). These cutaneous mechanoreceptors detect the application of and changes in the application of load on the plantar surface during walking. Hennig and Sterzing [2] reported that the plantar surface was more sensitive to touch perception than the heel.

Electrophysiological studies have shown that the cutaneous afferents from the plantar surface project on the somatosensory cortex leading to a perceptual representation [3]. There are several studies indicating that plantar cutaneous load receptors contribute to controlling standing balance and postural reflexes in healthy subjects [4–11] and in patients with multiple sclerosis [12] and Morbus Parkinson [13]. Indeed, balance problems are often related to cases where reduced plantar sensitivity occurs, albeit other sensory inputs are also affected (e.g. proprioception). The underlying relationship between the load experienced by the plantar surface, which can be easily manipulated by insoles and shoe materials, and the afferent signals from the plantar surface has not been investigated, although there is a long standing recognition of its importance for clinically relevant movement or balance tasks [14,15]. Studies [16–23] have generally indicated positive effects of standing on textured surfaces on motor task performance. The textures tested comprise areas of variable

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hardness (soft/hard) and are assumed to enhance or diminish plantar sensation and afferent signals in some way. Reports of a nil effect of texture [24] might suggest the site under the foot and extent of variation in load are important variables. Furthermore, since this is a neurophysiological rather than purely mechanical issue, the plasticity of the plantar sensation in response to altered plantar loads is also relevant, and this has not yet been investigated.

The aim of this initial study in healthy subjects was to test the hypothesis that by changing plantar loads (by using metatarsal pads of contrasting hardness) the sensitivity of the plantar surface of the foot might be affected over time. We supposed that hard metatarsal pads used for foot-related problems in patients could increase the sensitivity of the plantar surface.

2. Materials and methods

The study was approved by the institutional Ethics Committee and written informed consent was obtained from all participants. Twelve self reported healthy female students (mean age: 23 ± 1 yr; mean weight: 57 ± 3 kg; BMI: 19.4 ± 0.4 kg m^{-2}), free of foot pain, were recruited as a convenience sample from a mainly female student population who represented the majority of our students. None were involved in exercise nor sport activities >4 h/week. Visual inspection of the plantar contact area during standing via a podoscope (Lumiscope, Coblenz SA, France) indicated all had normal-arched feet (i.e. evidence of some but not a large contact area in the lateral midfoot area). All subjects had normal detection thresholds to light touch measured with 10 g Von Frey monofilaments.

2.1. Materials for metatarsal pads

Computer randomisation was used to allocate participants to soft (latex foam, ShoreA 11) or hard metatarsal pad (thermoplastic ShoreA65) groups (Coblenz SA, Stains, France). The metatarsal pads were identical in shape and depth and differed only in their hardness. They were mounted under the metatarsal heads on a 1.2 mm flexible base insole (Podiaflex ShoreA 90, Podiatech Sidas Medical, Vairon, France) (Fig. 1).

To quantify the physical characteristics of the two pads, uniaxial indentation tests were performed on 10 mm-thick material samples using an MTS (London, GB) hydraulic compression system with a U-shaped indenter (weight: 7500 g; length: 50 mm; diameter: 20 mm). The indenter was instrumented with a 5 kN force transducer. Each material was submitted to 4 quasi-static compressions, followed by 4 dynamic compressions with an indenter speed of 2 m s^{-1} and compression frequencies of 1, 4 and 17 Hz. A finite element (FE) model of each material was made after frontal and transverse plane symmetry simplifications were made. Force versus displacement experimental curves (from indenter tests) were used to perform inverse analysis of the mechanical responses and compute material properties. A generalised KV material law (Radioss v11, Altair, USA) was chosen as the model is adapted to visco-elastic foams. Parameters to quantify materials

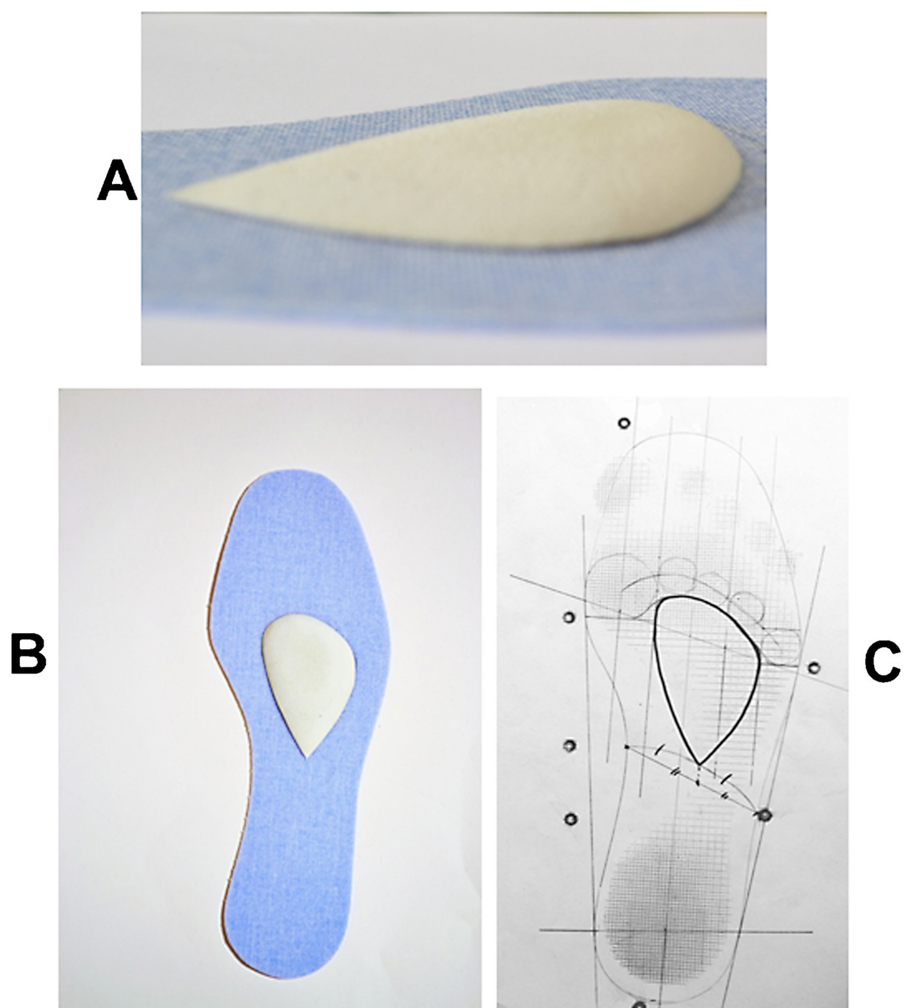

Fig. 1. Lateral (A) and upper view (B) of metatarsal pads and their projection on the foot sole (C).

Table 1
Parameters of interest for material classification.

	Df (mm)	Avib (N)	Tunload (ms)	*E* (J)
Hard pad	5.65	77	111	21,485
Soft pad	9.40	40	124	21,955

Df, maximal deflection of the sample; Avib (N), maximal amplitude of the [100–300 Hz] component of the force signal recorded at the lower surface of the sample; Tunload (ms), unloading time that is the time necessary for the force to fall back to zero from the peak value during indentation experimental tests. *E*, total amount of dissipated energy.

energy dissipation, rebounding and anti-vibration properties were extracted from the FE model (Table 1).

2.2. Protocol

Each participant had insoles for both feet. All participants wore without socks the same flexible, lightweight shoes with a low-heel (3 cm) and leather sole. Both groups were asked to continue normal daily activities and wear the insoles throughout each day (i.e. >10 h/day). Physical activity of participants (number of steps and the distance covered each day) was measured using pedometers (ONStep 100 Geonaute, Decathlon, France).

2.3. Measures of sensation

All subjects had normal detection thresholds to light touch measured with Von Frey monofilaments.

To test somatosensory stimulation thresholds, the participant lay flat on a bed, the ankle and foot of one side on a rigid horizontal support, the ankle fixed with straps at 90°. Mechanical stimuli were randomly applied to the heel or metatarsal area using a bespoke electronic stimulator device [25]. The stimulator delivered rectangular pulses of 100 ms duration which drove a mechanical probe via a solenoid. The probe tip (area 0.07 cm^2) protruded 0.5 cm into the skin surface. A strain gauge was used to calibrate the mechanical pulses. Four mechanical stimuli (24, 41, 69 and 116 g) were delivered in random order, producing local plantar pressures of 3.36, 5.74, 9.67, and 16.26 N cm^{-2}. This bespoke apparatus was previously validated to estimate tactile stimulation of the fingers [25] (Fig. 2). Both feet were tested.

For the auditory stimulation (a sham test), the participant was in the same position and wore headphones. Four sound-pressure levels (20, 30, 40 and 60 dB) of the same frequency (2 kHz) were used. Intensities ranged from the sound-pressure of a murmured voice to that of talk perceived at 1 m [26]. We determined which ear detected the lowest intensity (20 dB) and used this ear.

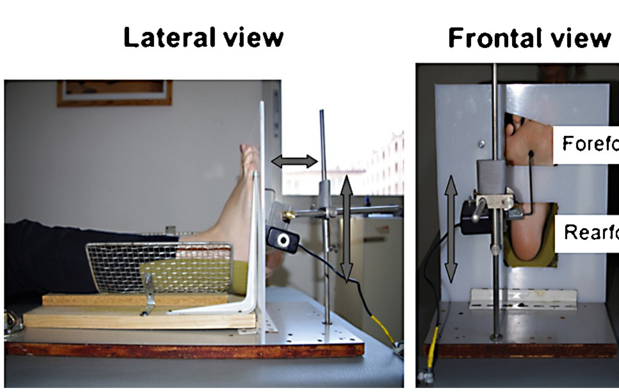

Fig. 2. The bespoke apparatus built to apply mechanical stimuli to the forefoot and rearfoot. The mechanical probe is driven by a solenoid and can be moved to apply load to the forefoot or rearfoot as required.

Measurements were taken at day 0 before allocating the participant to an insole group and at day 8 and day 30. All measurements of sensation were performed between noon to 2 p.m and within 30 min of removing shoes. The measurement task for each participant was to judge the magnitude of the 4 different mechanical stimuli (pressures) randomly applied to the central metatarsal heads (i.e. the site where the metatarsal pad was placed) or the heel area (somatosensory stimulation) or to judge the different sound-pressures (auditory stimulation). The same area of the forefoot and rearfoot was stimulated within and between participants. Judgements of stimuli were recorded on a 0–10 cm visual analogue scale. Participant specific standards for 0 and 10 on this scale were established in pilot tests in which the lowest and highest stimuli (mechanical pressures on the foot and sound-pressures for audible tests) were presented twice in order to acquaint the subjects with the full range of loads/sounds. After this acclimatisation the experimenter remained silent during further tests and participants indicated their estimate (0–10) immediately after the test. Mechanical pressure loads or sound pressure loads were repeated in a random sequence ensuring that each mechanical (foot) and sound (audio) stimuli had been applied 6 times.

The Stevens power law [27], $\Psi = k \times \Phi^n$, where Ψ is the estimate and Φ is either the true somatosensory stimuli or sound-pressures, was used to quantify the perceptual performance at day 0, 8 and 30. As commonly performed [25,27], the exponent n in the power law was determined by a linear regression analysis between Napierian logarithmic (Ln) transformed stimuli and estimation data. Regressions were obtained for each test performed in each individual and the significance against zero of the r coefficient was tested. The scattering of pair values collected for each run was estimated by the standard errors of both Ln k and n coefficients of $\text{Ln}\,\Psi = \text{Ln}\,k + n \times \text{Ln}\,\Phi$ regression with 95% confidence intervals. All k values were negative and thus any decrease in k indicated an elevated sensitivity to the lowest loads. The n coefficient is the slope of the Stevens power law and measures the changes in perception between the extreme values of loads.

2.4. Statistical analyses

Data are presented as the mean and standard error of mean (SEM). The normal distribution of the variables was verified with the Kolmogorov–Smirnov test. Least square regressions with 95% confidence intervals between perception (Ψ) and mechanical or sound pressure loads (Φ) were computed in each subject and for each epoch of the protocol (day 0, 8, and 30). In each participant, changes over time in the slopes (n) and ordinate intercept (Ln k) of regressions were tested using ANOVA for repeated measures when the variables were normally distributed, or a Friedman's test for repeated measures when they were not. Differences between data at 0, 8, and 30 days were identified using the Tukey's multiple comparison test. Significance was accepted if $p < 0.05$.

3. Results

3.1. Material properties

The hard pad deformed 40% less than the soft pad (i.e. was stiffer) and had higher energy dissipation (Eimp) (the hard pad was a poorer shock absorber) (Table 1). The hard pad had more than double the dV (i.e. was slower to recover its shape), but was largely comparable to the soft pad in terms of Tunload and energy loss values. Both pads were found to be good filters against vibration (low Avib).

3.2. Daily activity of subjects

The mean daily activity was 5102 (±396) steps and 4.5 (±0.6) km and activity was not statistically significant different between groups. The pedometer was not able to differentiate walking, running, or stair climbing. However participants did not report occupational nor leisure activities that were notably different.

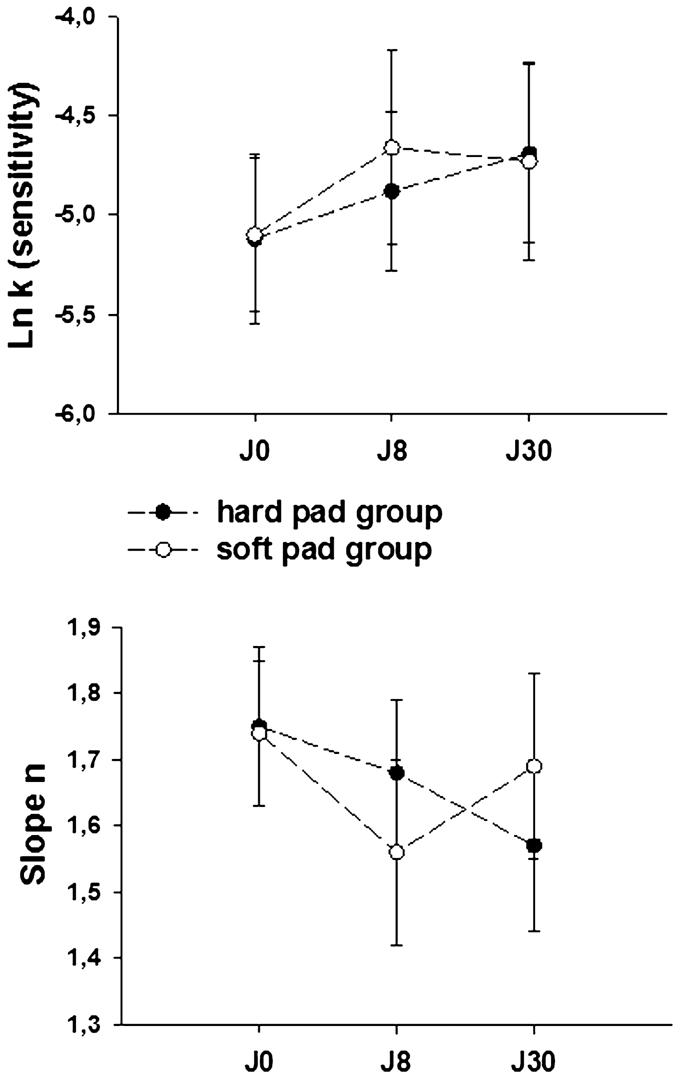

Fig. 3. Mean ± SEM values of n and $\mathrm{Ln}\,k$ coefficients of $\mathrm{Ln}\,\Psi = \mathrm{Ln}\,k + n \times \mathrm{Ln}\,\Phi$ regression equations obtained for the auditory sensation measured before (control) then after 8 and 30 days of daily activities with hard or soft metatarsal pads. No significant differences were noted over time.

3.3. Sham test (auditory sensation)

For auditory sensation there were no statistically significant variations in the n and Ln k coefficients of the Stevens power law (Fig. 3). This indicates that participants were able to maintain consistent feedback in response to the audible stimuli over 30 days.

3.4. Somatosensory sensation

At day 0, there was no significant difference in Ln k and n coefficients of the Stevens power law between the forefoot and rearfoot (Fig. 4). At day 30, there was statistically significantly elevated sensitivity (ascent of the ordinate intercept, Ln k) compared to day 0 ($p < 0.05$) for the forefoot in the hard metatarsal pad group but not the soft metatarsal pad group (Fig. 4). This increased sensitivity was not observed for the rearfoot. No significant changes in n coefficient were measured in the hard or soft metatarsal pad groups (Fig. 4).

4. Discussion

The present study in healthy participants, wearing the same shoes, suggests that 30-days use of a hard metatarsal pad can lower the sensitivity threshold for detection of small loads applied to the forefoot. It is tempting to speculate that this means people could detect lighter plantar loads and thus have greater tactile acuity. This could be clinically meaningful since the application of plantar load might be detected earlier and thus input to motor task control could be enhanced. We attribute this effect to the properties of the hard metatarsal pad because the soft pad produced no change in sensitivity, nor did the rearfoot sensitivity change in the hard metatarsal group. It is not possible to know which material property (e.g. dV, Tunload etc.) creates the effect but this information is provided here to fully understand the material studied.

Our study has some limitations which are pertinent to the interpretation of the work. (1) the participants were female and some have reported gender differences in plantar sensitivity for vibration but not for touch [2]; (2) we did not compare the changes in sensory perception using established clinical methods such as monofilaments or vibration devices; (3) diurnal changes in plantar sensation [28] suggest that our observations may not represent effects of increased load throughout the day; (4) we did not measure the temperature of the feet during measurements of sensation and it is well known that reduced plantar foot temperature modifies pressure distribution patterns and gait [9–11]. However, the room air temperature was the same throughout (22–24 °C); (5) we studied healthy participants and the effect of foot insoles on plantar sensation in patients with different foot types, plantar loading patterns and foot disease may differ; (6) the repetition of the psychophysical tests (control, 8th and 30th days) could have elicited learning processes. However, the estimation of sound pressure loads did not vary over the 30 day protocol in either group suggesting that any learning effect was minimal. Earlier tests in four female volunteers who did not wear insoles showed that the plantar sensation tests did not significantly vary over 30 days.

The mechanical stimuli applied are at the lower end of the sensitivity range of the plantar surface and these may not feature strongly during motor tasks such as walking. However, the mechanical stimuli tests rely upon applying loads that have low detection states, since it is this "non" detection that an improvement in sensitivity might affect. Applying high loads that everyone can always detect would be an insensitive measure of plantar sensitivity and have limited capacity to be responsive to factors that might change in plantar sensitivity.

We have associated the change in sensitivity with the hardness of the metatarsal pad and assumed the harder pad increased pressure more than the softer pad. We did not quantify the change in pressure but Lane and coworkers [15] have reported that the increase in ShoreA values in shoe soles from 25 to 58 ShoreA (compared to 55 in this study) produced proportional increase in plantar pressure under the forefoot, midfoot, and rearfoot. We only changed materials for the forefoot. However, combining rearfoot and forefoot effects might be more beneficial for walking and standing tasks since both areas are used.

We assume that applying more load with the hard material sensitised the sole receptors. It is unclear whether more load could further increase sensitivity, or whether it is the load applied or the load differential between pad and adjacent areas that was important. The change in sensitivity occurred after 30 days but was absent at 8 days, suggesting a reasonable level of continuous insole use is required and thus that the plasticity of plantar sensation needed more than 8 days to occur. Likewise, although we did not investigate the role of physical activity on the change in sensitivity, we expect there is a minimum level of activity required. The "dose" of load provided by the pad is the culmination of the material properties, the subsequent change in load experienced with each step, the number of steps taken with the pad each day, and the number of successive days during which these steps are taken.

Very few previous studies have investigated insole-induced changes in somatosensory sensation of the sole. Indirect observations suggested that wearing textured [21–23], spiked insoles [29,30] or shoes designed for use in 'Formula 1' [20] could modify the sensory

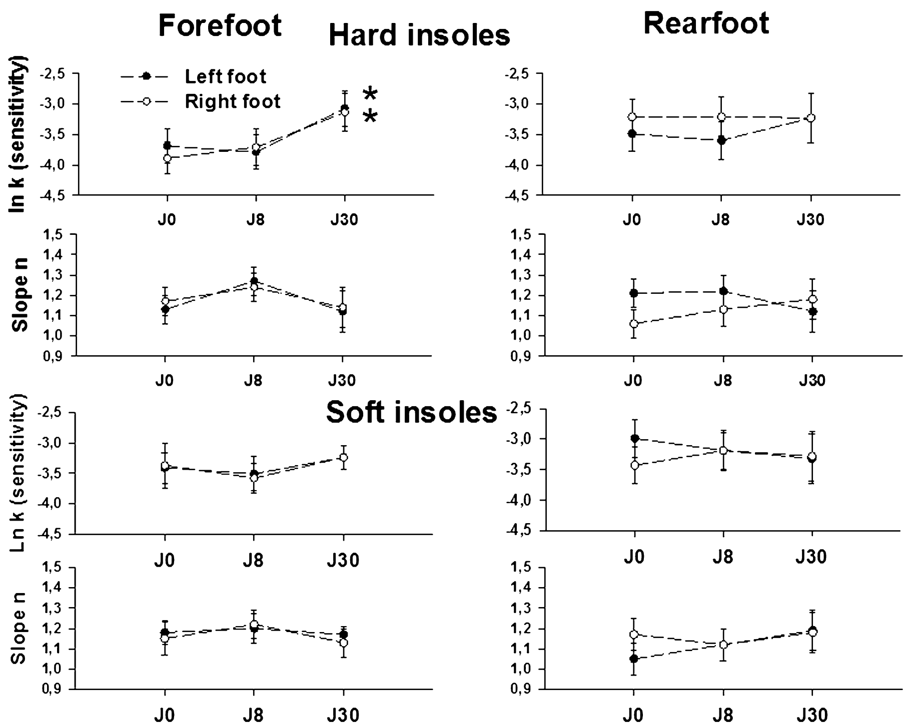

Fig. 4. Plantar sensitivity at 0, 8 and 30 days in the hard metatarsal pad group (upper diagrams) and soft metatarsal pad one (lower diagrams). *Significant variations of the mean ± SEM of Ln k values measured in each subject at the 30th day compared to day 0 data ($p < 0.05$).

information from the sole of the foot. No quantitative measures of sensitivity were taken in this previous work but alterations in the gait pattern were reported. Priplata et al. [31] used vibrating gel-based insoles as noise-based devices and reported significant improvement in balance control in young and older subjects. Thus, different situations (textured, spike or vibrating insoles) appear to modify the sensory inputs from the sole.

The results from this pilot study suggest some plasticity in plantar sensitivity is possible. The metatarsal pads improved the ability of the participants to detect the lowest pressure stimulus applied on the forefoot (24 g, i.e. 343 g cm^{-2}). These small loads are likely in the range experienced at the periphery of the contact area under the foot when standing and as such could enhance detection of changes in contact area, possibility an important marker for instability. This might also be useful in the detection of short duration and low load events at initial contact and toe off when walking. Thus, insole-induced increases in somatosensory sensitivity could be important for motor tasks. However, whether sensitivity can be further manipulated with variable changes in insole properties and how induced changes in sensitivity relate to specific motor tasks warrants more systematic investigation.

The physical characteristics of the pressure stimulus we applied on the sole may have some importance in studies of this nature. Because they consisted in square waves of short (100 ms) duration, it may be supposed that the mechanical stimuli preferentially activated the fast-adapting cutaneous receptors. As shown by Kennedy and Inglis [1], the proportion of fast-adapting receptors, the Meissner and Pacinian corpuscles, is high in the sole (71% of tested units) and these receptors are mostly present in the forefoot. The fast adapting type I Meissner receptors have small receptive fields, while the fast adapting type II Pacinian receptors have large receptive fields. The rod tip of our pressure generator having a relatively large area (0.07 cm^2), we may suppose that our mechanical foot sole stimulation could activate both types of fast-adapting receptors. The fast adapting mechanosensitive receptors usually give little information on the scale of the stimulus, explaining the absence of changes in the n coefficient (the slope of Steven's power law regression) which measures the differentiation of the loads.

5. Conclusions

Our study in healthy women has highlighted the influence of different insole materials under the forefoot on plantar somatosensory sensation. Use of a harder metatarsal pad increased the ability of the forefoot to detect low loads. Further studies investigating the mechanism involved in creating this change in plantar sensitivity, and how such change might affect motor tasks, is now warranted. Data in the literature suggest that balance problems can be related to reduced plantar sensitivity in healthy subjects [4–11] and patients [12,13]. We hypothesise that the increased plantar sensitivity when wearing metatarsal pads should improve motor tasks. Non-invasive psychophysical measurements of the sole sensation have been demonstrated as a tool to explore the somatosensory pathways related to plantar sensation, and could have useful application in a range of clinical groups (e.g. diabetes, older people).

Conflict of interest statement

All authors disclose any financial and personal relationships with other people or organisations that could inappropriately influence the present work. Nester is employed by the University of Salford which has a commercial interest in a spinoff company that produces insoles. Nester also has an equity share in that company. The insoles tested have no connection to that company.

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