Title:

Effects of a range of six prefabricated orthotic insole designs on plantar pressure and gait mechanics in a healthy population: a randomised, open-label cross-over investigation

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Abstract:

Background: Prefabricated orthotic insoles are widely commercially available and can be easily self-selected by the general population to treat foot and lower body musculoskeletal pain without requiring advice from a healthcare professional. Although they are generally designed to mimic traditional design features of custom-made orthotics used in clinical practice, the effects of prefabricated insoles on plantar pressure distribution and gait mechanics are poorly understood.

Aim: The aim of this investigation was to evaluate and directly compare a range of 6 different commercially available orthotic insoles, to understand how each of the prefabricated insole designs affect gait and plantar pressure in healthy individuals.

Methods: This was a single centre, randomised, open-label, cross-over investigation. In-shoe dynamic pressure (F-scan) and lower limb biomechanics (3D motion capture and force plates) were investigated in 24 healthy subjects with normal foot posture, wearing standard shoes alone and in combination with 6 different orthotic insoles, consecutively, measured on a single day. The biomechanical impact of each orthotic device was determined by the statistical significance of changes from baseline measurements (standard shoe alone) for each of the 6 investigational insoles.

Results: The orthotic insoles in this range had limited effects on gait biomechanics when compared with the control shoe, however insoles with heel cups and medial arch geometries consistently increased contact area

(CA) at medial arch and whole foot regions and reduced both peak plantar pressure (PP) and pressure time integral (PTI) at medial arch and heel regions.

Conclusions: This investigation has aided in further understanding the mode of action of prefabricated insoles in a healthy population. The insoles in this study redistributed plantar pressure at key regions of the foot, based on design features common to prefabricated insoles, yet there was no evidence that gait mechanics were impacted; an important consideration for the general population, for which unintended alteration of gait could be detrimental. Commercially available prefabricated insoles could therefore represent an easily accessible means of reducing lower body musculoskeletal stress for those who spend prolonged periods of time on their feet.

Keywords: Orthotic insoles, prefabricated insoles, foot orthoses, biomechanics, gait, plantar pressure.

Background:

Orthotic insoles: custom vs. prefabricated

There are many different types of foot orthoses available for the treatment of foot and lower body musculoskeletal (MSK) pain, ranging in complexity from generic 'off-the-shelf' heel pads and prefabricated insoles to custom ('custom-made') foot orthoses. Differentiating between the broad variation of orthotic insoles used in both clinical practice and research can be confusing, especially as consistent terminology is not always used in the literature [1]. Furthermore, differences in orthotic design features, material hardness/firmness, and the addition of posting or wedging intended to tilt the device from the horizontal make their direct comparison particularly challenging [2, 3]. As such, orthotic insoles are commonly separated into two categories based on their method of manufacture; custom or prefabricated.

Typically, custom orthotics are contoured, removable in-shoe devices that are fabricated to practitioner-prescribed specifications and fitted by health professionals [4]. Due to their patient-specific nature, the choice of custom insole design can vary largely among foot experts [5], however they are a well-established method of treating lower body pain (particularly foot pain) in a clinical setting [1, 2, 4]. In contrast, prefabricated orthotic insoles are generic devices designed to incorporate key design features of custom orthotics [5], and although their use is comparatively less well-studied and well-accepted, the commercial availability of such ‘over-the-counter’ devices makes them an easily accessible self-select treatment option for the wider population [6]. This raises the need to acknowledge that a key difference between the two insole types is often the level of expertise which sits behind their selection; for those who experience MSK pain but do not seek the advice of a trained healthcare professional, selection of appropriate orthotic insole features can be difficult. It remains to be determined whether this population benefits significantly from prefabricated orthotic insole use.

Design features & material properties of orthotic insoles

Custom orthotic insoles are inherently variable by design, yet they frequently possess very similar shapes and are capable of producing similar plantar pressure redistribution [5]. Stolwijk et al., [5] suggest that “basic insoles could be sufficient for particular patient groups”; this is the premise that underpins generic prefabricated insole design. It is therefore important to recognise that whilst it is easy to group orthotic insoles as ‘custom’ or ‘prefabricated’, significant overlap exists between the two in terms of their design features and material properties. Both groups utilise basic traditional orthotic design features that are commonly used in clinical practice; midfoot (arch) support, heel cups, heel raises, metatarsal cushioning, and posting or wedging.

Another variable is performance of the insole material. Soft and flexible orthoses typically provide immediate ‘comfort’ and cushioning and may lead to increased plantar pressure reduction [7], whereas semi-rigid orthoses have a higher hardness/firmness and are designed to provide structure and support to the foot [3, 8]. It could therefore be argued that the design features and physical attributes of orthotic insoles should be considered above simply their method of manufacture. Indeed, the overarching mode-of-action of orthotic insoles is reliant on these common characteristics, utilised in varying combinations. This may help to explain why recent studies have reported comparable efficacy between custom and prefabricated designs [6, 9, 10].

Clinical evidence of the efficacy of orthotic insoles

There is continuing debate over the efficacy of prefabricated versus custom orthotics [1]; a debate that the huge variety of prefabricated orthotic insole designs does little to simplify. A growing body of evidence suggests that prefabricated orthotics are effective in reducing pain across many lower body MSK pain types including foot, heel, knee, leg and lower back pain [9, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20], with improvements in both pain and function comparable to that of traditional custom orthotics for indications such as heel pain [9, 6, 10].

The benefits of orthotic insole use span far wider than simply those with diagnosed pain conditions in a clinical setting. For example, the efficacy of orthotic insoles has been clearly demonstrated in populations who spend significant periods of time 'on their feet' during their working day, with studies reporting reduced MSK pain in police officers [21], soldiers [22], naval recruits [23], nurses [24], factory workers [16], and others whose jobs involve prolonged standing [11, 25, 26, 27] or long-distance walking [28]. As such, orthotic insoles are proposed to alleviate mechanical stresses associated with prolonged walking and standing; major contributors to overuse injuries and lower body MSK pain [29, 30,31, 32).

The mode-of-action of orthotic insoles: evidence of biomechanic effects for prefabricated orthotic insoles

Despite the common and well-accepted clinical use of orthotic insoles as a means of treating lower body MSK pain, their physiological basis or 'mode-of-action' is not yet well understood. Little comparative experimental data exists on the biomechanical impact of various orthotic designs, or indeed how these features translate to clinical success [5, 33]. Meta-analysis of potential mechanisms of foot orthoses revealed two key paradigms that have emerged from the literature: the s*hock attenuation paradigm* and the *kinetic paradigm* [3]. Mills et al., [3] explain that the shock attenuation paradigm is based on the concept that orthoses "reduce the magnitude of impact force by acting as a cushioning interface between the ground and the foot", whereas the conventional kinetic paradigm is based on the hypothesis that orthoses "normalise excess pronation and subsequent coupled movements in the lower body (e.g. internal tibial rotation)". Both paradigms, whilst separate, can simultaneously contribute to how orthotic insoles are able to alleviate MSK pain, therefore orthoses are usually prescribed with the aim of optimising foot mechanics and function, and/or for providing cushioning and off-loading of foot structures [7].

The *shock attenuation* paradigm is linked primarily to peak plantar pressure; Stolwijk et al.,[5] state "it is assumed that foot pain can be successfully relieved by redistributing the (peak) plantar pressure under the painful areas of the foot … the question remains however, whether pressure reduction requires a specific type of insole". For prefabricated insoles, data in the literature regarding their impact on plantar pressure is variable and seemingly dependent on geometric design, with some studies reporting reduced peak plantar pressure in the forefoot [34] and others reporting increases in forefoot and midfoot plantar pressure [8, 35].

According to the *kinetic paradigm*, orthotic insoles are generally required to significantly affect gait in order to be efficacious, therefore they often aim to control excessive or abnormal motion of the foot [8], and yet their precise effect on gait mechanics is poorly understood. It has been suggested that the biomechanic changes produced by custom orthotics are more pronounced [36] and improvements in gait persist for longer than those generated by prefabricated orthotics [37], however relatively few studies have evaluated the gait changes offered by prefabricated orthotics, providing little convincing evidence of significant gait alteration [7, 9, 36, 37]. There is a need for further research to address this and the subsequent implications for the efficacy of prefabricated insoles in the treatment of lower body MSK pain. For the general population purchasing over the counter prefabricated insoles to treat mild foot or lower body pain, or for those looking to reduce the MSK stresses of prolonged standing or walking, the necessity for alteration of gait is often unclear.

Summary and study objectives

There is a lack of consistent evidence to demonstrate the impact of prefabricated orthotic insoles on plantar pressure or gait mechanics. Although they are generally designed to replicate the traditional orthotic design features utilised in clinical practice, there is huge variation in the geometry and material properties of prefabricated insoles. To the authors knowledge, there has been no focus to-date on the comparative effects of a range of prefabricated orthotic insoles on the biomechanics of a healthy population; therefore, the aim of this investigation was to consecutively investigate and directly compare the impact of 6 different prefabricated orthotic insole designs on both gait mechanics and distribution of plantar pressure in a healthy population with normal foot posture.

Methods:

2.1 Participants

Twenty-four healthy male and female participants between the ages of 18-60 years, with a body mass index (BMI) between 18.5 to 24.9 kg/m^2 and shoe size between 4.5 to 11 (United Kingdom)/ 37 to 45 (European), were included in this investigation. Written informed consent was obtained from all participants, along with baseline demographic information and relevant medical and medication history. A physical examination and assessment of the subject's anatomy and biomechanics was performed and Foot Posture Index (FPI) [38] was determined; participants were included if they had a FPI between 6 and 9 showing mild pronation, did not have any walking impairments, and could walk without distress (as determined by walking at a speed of 3-5 km/h for a distance of 30 meters). A urinary pregnancy test was performed for female subjects.

Participants were excluded if they had leg-length discrepancy of more than 5mm, a medical condition that could compromise the use of the orthotic insoles (peripheral vascular disease or sensory neuropathy), current or previous injury (that had prevented usual activity for more than 3 weeks in the last year), foot pain, or broken/irritated or damaged skin on their feet. Individuals who used prescribed or self-administered orthotics, had consulted a healthcare professional for a gait-related or foot pain issues, or those who had a history of lower limb or foot surgery were also excluded from the study.

2.2 Experimental protocol:

This was a single centre, open-label, cross-over investigation conducted at the Laboratoire d'Analyse du Mouvement Humain, based in the Department of Mechanics and Civil Engineering of Université de Liège Sart Tilman, located in Liège, Belgium. In-shoe dynamic pressure and lower limb biomechanics (3D gait and force plate analysis) were investigated in 24 healthy subjects wearing neutral standard shoes in combination with 6 prefabricated orthotic insoles consecutively, in a randomised order, measured on a single day. The biomechanical impact of the investigational insoles was assessed by the statistical significance of changes from baseline measurements in the standard shoe alone when compared to each test insole.

2.2.1 Standard shoe

The control was the standard unisex shoe (Converse All Star Ox [M7652C Optic White], Converse, USA) worn with the manufacturer's EVA insole removed (referred to as Device G or 'standard shoe alone'); the standard shoe did not have any specific design features that reduced the effects of pronation.

2.2.2 Prefabricated orthotic insole range:

A range of 6 prefabricated orthotic insoles (Scholl InBalance Pain Relief insoles, Scholl's Wellness Company, UK) were investigated (Insoles A-F: Figure 1; Table 1). Each insole had neutral rearfoot posting and differed in design, either by material properties and/or geometry; insoles were fabricated from a combination of ethylene vinyl acetate (EVA), polyurethane (PU), thermo plastic elastomer (TPE), or thermoplastic polyurethane (TPU) and incorporated design features such as arch support, heel cup, and heel and metatarsal pads (Table 1). The range was developed to alter the forces acting on the foot and lower body in order to relieve a range of foot and lower body MSK pains, with an overarching triple mode of action consisting of; 1) shock absorption, 2) redistribution of plantar pressure, and 3) improvement of foot stability. Four of the six insoles in the range are commercially available and intended to be self-selected by an adult population experiencing mild intermittent MSK pain as a consequence of prolonged periods of standing or walking. The range is not intended to be used for the treatment of severe pain, injury, or biomechanical gait abnormalities.

2.2.3 Randomisation:

Eligible subjects were randomised to a sequence which defined the order in which the pair of insoles and standard shoe alone were to be tested. The sequence of allocation was based on a 7x7 Latin square design.

2.2.4 Fitting of the standard shoe and insoles:

The standard shoe was assigned based on the participants normal shoe size. Orthotic insoles were placed directly inside the standard shoe (without the original shoe insole) and cut to fit the size and shape of the standard shoe by the podiatrist. Subjects walked around for approximately 20 meters in order to get a stabilised gait after each insole was fitted in the standard shoe. The investigator and subject each assessed the fit of the insole prior to the assessments. If there was a problem (i.e. discomfort) identified the insole was re-fitted into the standard shoe and subjects were asked to walk around to check that the new positioning had resolved the problem.

2.2.5 In-shoe dynamic pressure:

In-shoe dynamic pressure measurements [F-Scan (wireless), Tekscan, Boston, USA] were applied to both feet and involved the subjects wearing a standard shoe alone (without insoles) and the standard shoe with each of the six prefabricated orthotic insoles. Standard in-shoe sensors with 3.9 sensels per cm^2 were used and cut to fit the size and shape of the shoe for each participant. Three regions were assessed – ball of foot (BOF), medial arch, and heel - defined using the automatic 3-box analysis algorithm of the acquisition software. Using the calibration procedure within the acquisition software, calibration of each foot was performed separately, with the subject standing still in an upright position with the shoes on. Data were sampled at 50Hz and processed using the F-Scan software (v7.50-07). Peak pressure (PP), pressure time integral (PTI) and contact area (CA) were assessed for each region. Participants were given a familiarisation period for each condition to determine the (subject specific) starting position, to have the feet land on the force plates naturally, and to allow the subject to feel comfortable with the environment; subjects were given the instruction to "walk at a self-chosen comfortable speed". Data were collected during three walking trials and a mean of the three was taken.

2.2.6 3D gait analysis (including force plate):

Three-dimensional gait analysis was conducted concurrently to the pressure data collection. Kinematic data were collected using a Codamotion system with three units at 100 Hz (CodaMotion, Charnwood Dynamics, UK) [44]. Synchronised kinetic data was collected using one force plate at 1000 Hz (Kistler 9281EA, Kistler Instruments Ltd. London, UK).

Prior to the walking trials a static calibration trial was recorded. This consisted of participants standing in a natural upright position and palpating anatomical landmarks then creating a virtual marker using a wand with four markers with known positions. Virtual anatomical markers were created for the anterior superior iliac spine, posterior superior iliac spine, lateral and medial femoral epicondyles, lateral and medial tibial condyle, lateral and medial malleoli, 1st and 5th metatarsal phalangeal. Whilst, active markers were placed on the thigh (four non-orthogonal markers), lower leg (four non-orthogonal markers) and calcaneus (three markers on a tripod) to track the motion of each segment during the dynamic walking trials. Subjects were then instructed to walk in a straight line (15 to 20m) to achieve a stabilized gait within the acquisition field; acquisition time was set to 15 seconds. For each condition (standard show alone and in combination with each of the 6 insoles), subjects performed one familiarisation trial and data was recorded for a subsequent 3 trials. A trial was accepted when the feet landed fully on the force plates.

Data were exported and processed using Visual3D (C-Motion, Inc., Germantown, MD, USA). A low pass Butterworth 4th order filter with cut of frequencies of 6 Hz and 25 Hz were used for motion and force data. A six degree of freedom model was used. Hip joint centers were calculated using anterior superior iliac spinae locations based on [39]. Knee and ankle joint centers were determined as the mid-point between the medial and lateral epicondyles and malleoli respectively. External joint moments were calculated using three-dimensional inverse dynamics. Estimated segment inertial and geometric properties were determined for each participant [40]. Joint moments were normalised to body mass (Nm/kg).

Joint orientation (rearfoot angle at contact, maximum rearfoot angle, rearfoot excursion, maximum pelvic tilt, maximum pelvic obliquity, maximum hip adduction) & kinetics (maximum vertical force, vertical impulse, maximum ankle inversion moment, maximum ankle eversion moment, maximum knee adduction moment, maximum hip adduction moment, maximum hip abduction moment) were determined.

2.2.7 Statistical analysis:

Continuous variables were summarised with means, standard deviations, and valid cases. Following the intention-to-treat (ITT) principle, all subjects participating in the study were included in the analysis of demographics, baseline, biomechanics and safety analysis wherever possible; subjects belonged in the ITT if they had used at least one insole.

For in-shoe dynamic pressure, right and left foot were analysed and summarised separately. For gait and force plate, analysis of within-subject differences of each insole compared to standard shoe alone were performed. Difference for each parameter of each insole to shoe alone measurements was calculated. Statistical significance was present when the 95% confidence interval did not include zero.

Figure 1: The range of 6 prefabricated orthotic insoles (Scholl InBalance Pain Relief insoles).

From left to right: Insoles A-F. Top side, underside and medial side views (not to scale).

Table 1: Orthotic insole range description, material composition and design features.

Orthotic insole	Design	Description & material composition	Design features
A	¾ length	Rigid orthotic insole made from EVA foam with inserted softer PU foam pads incorporated into the heel area.	Medial arch support and heel cup.
B	¾ length	Slim shaped orthotic insole made from PU foam with inserted softer PU foam pads incorporated into the ball of foot and heel area.	Medial arch support and metatarsal dome.
C	Full-length	Shaped orthotic insole made from PU foam with inserted softer PU foam pads incorporated into the ball of foot and heel area.	Medial arch support and heel cup.
D	Full-length	Shaped orthotic insole made from EVA foam with inserted softer PU foam pads incorporated into the ball of foot and heel area.	Medial arch support and heel cup.
E	Full-length	Shaped rigid orthotic insole made from EVA foam with a ¾ length hard shell injected with TPU, with softer PU foam pads incorporated into the ball of foot and heel area.	Medial arch support and heel cup.
F	Heel cup	Horseshoe shaped flexible gel heel cup (TPE), with softer TPE gel pad in the heel area.	Medial arch support, flexible heel cup and heel raise.

(PU = Polyurethane, TPE = Thermo Plastic Elastomer, EVA = Ethylene Vinyl Acetate, TPU = Thermoplastic polyurethane).

Results:

3.1 Participants:

A total of 24 subjects were included in this investigation; one subject withdrew consent before completing all assessments. Subject age ranged from 20 to 55 years with an overall mean of 36.1 years and a standard deviation (SD) of 10.82 years. Sex was balanced in the overall population (11 men, 13 women). All subjects were of white ethnic origin. The overall mean height was 1.7m (SD = 0.09, range = 1.54-1.88m), the mean body mass was 63.63kg (SD = 10.12, range = 44.0-88.0kg), the mean body mass index (BMI) was 22.03kg/m^2 (SD = 2.02, range = 18.6-24.9kg/m^2), and all subjects were within the required foot posture index (FPI) range of 6-9 (mean = 6.6, SD = 0.93).

3.2 In-shoe dynamic pressure:

The in-shoe dynamic pressure was measured in 23 subjects. Changes in PP, PTI and CA per insole compared with shoe-alone are presented in Figure 2 and summarised in Figure 3; variability between insoles and anatomical areas of interest (ball of foot, medial arch, and heel) were observed:

3.2.1 Force and pressure:

3.2.1.1 Peak pressure - PP

PP was consistently reduced for the majority of insoles across the ball of foot, medial arch and heel regions (Figure 2 [panel 1]; Figure 3). Most notable was the impact on PP at the heel area, which was reduced across all of the insoles and statistically significant in both feet for insoles B-E. Insoles B-E also demonstrated statistically significant reductions in PP at the medial arch in one or both feet.

3.2.1.2 Pressure Time Integral – PTI

PTI measurements were consistently reduced at the heel and medial arch regions across the insole range (Figure 2 [panel 2]; Figure 3). The most significant changes were noted in the medial arch area for insoles A-E; statistically significant decreases in PTI were observed for both feet. At the heel region, a statistically significant reduction in PTI was observed for all insoles in either one (Insoles D-F) or both feet (Insoles A-C).

3.2.1.3 Contact area - CA

CA for medial arch and whole foot regions was statistically significantly increased, in either one or both feet, for Insoles A-E (Figure 2 [panel 3]; Figure 3). For Insole F, CA at the medial arch was statistically significantly reduced in both feet, and CA across the whole foot was not significantly changed (Figure 2 [panel 3]: Figure 3).

3.3 Gait and force plate analysis:

The gait and force plate analyses were performed on 24 subjects. Insoles C, D and E were not measured in one subject because the subject withdrew consent part-way through the assessments; analysis was based on observed data only, there was no imputation of missing data.

3.3.1 Kinematic data

Kinematic data is provided in Table 2. Joint orientation was not statistically significantly changed for the majority of measures across the 6 orthotic insoles in this investigation. Statistically significant changes were observed in insole F only: hip adduction was decreased unilaterally, and pelvic obliquity was increased.

3.3.2 Kinetic data

Kinetic data is provided in Table 3. Significant changes were noted for ankle inversion, ankle eversion and knee adduction moments for insoles A, C, D, E and F. Hip adduction moment was increased for insoles A and B. Insole B did not impact gait and demonstrated an absence of any consistent statistically significant changes in kinetic data.

3.4 Safety results:

No adverse events, adverse device effects or device deficiencies occurred during this clinical investigation.

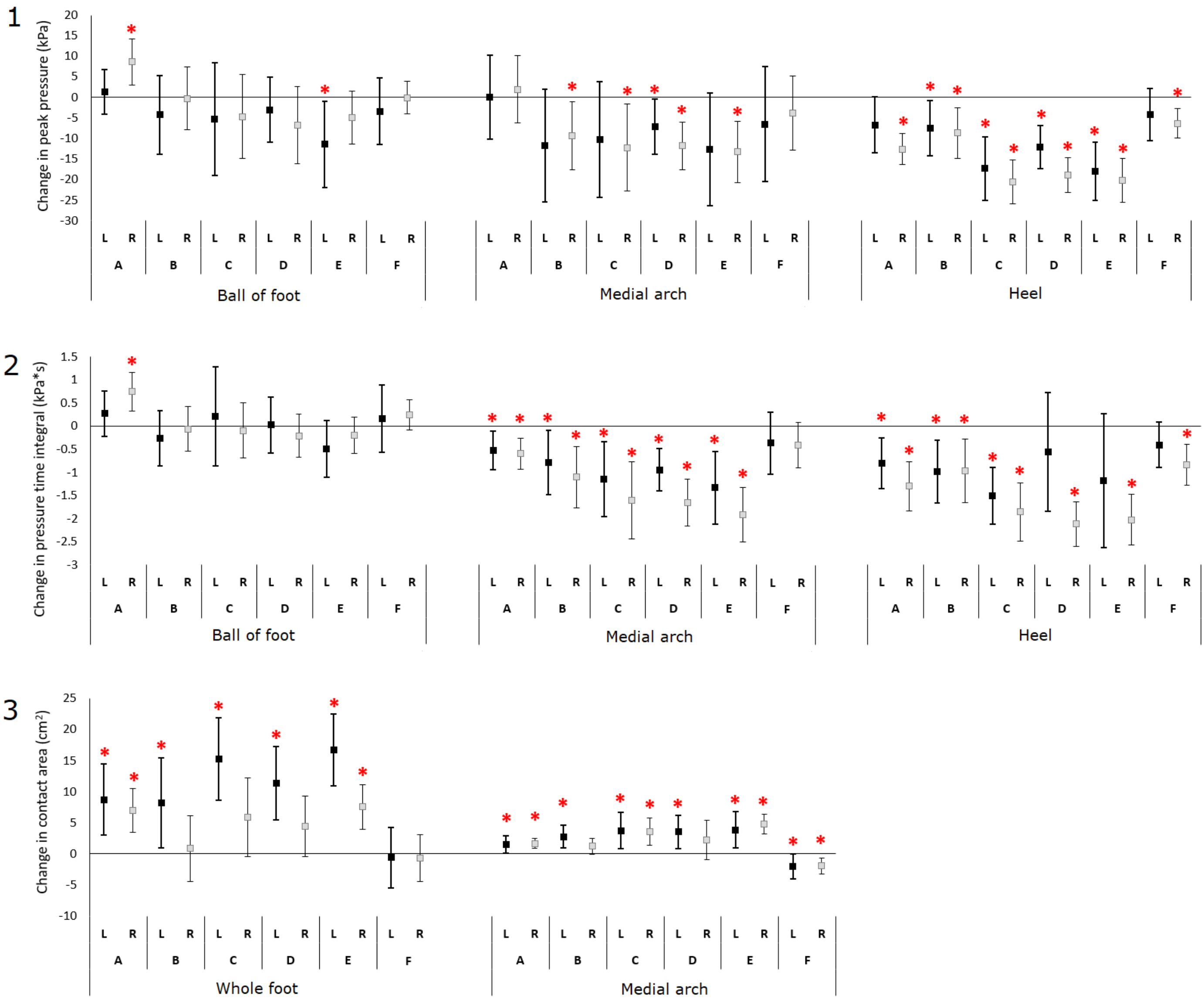

Figure 2. Force and Pressure.

Change in Peak pressure [PP] (Panel 1), Pressure time integral [PTI] (Panel 2), and Contact area [CA] (Panel 3), from standard shoe alone; measured at ball of foot, medial arch, heel and whole foot regions where indicated. Insoles indicated by letters A-F. L = left, R = right. (n=23). Asterisks indicate statistical significance; present when the 95% confidence interval did not include zero.

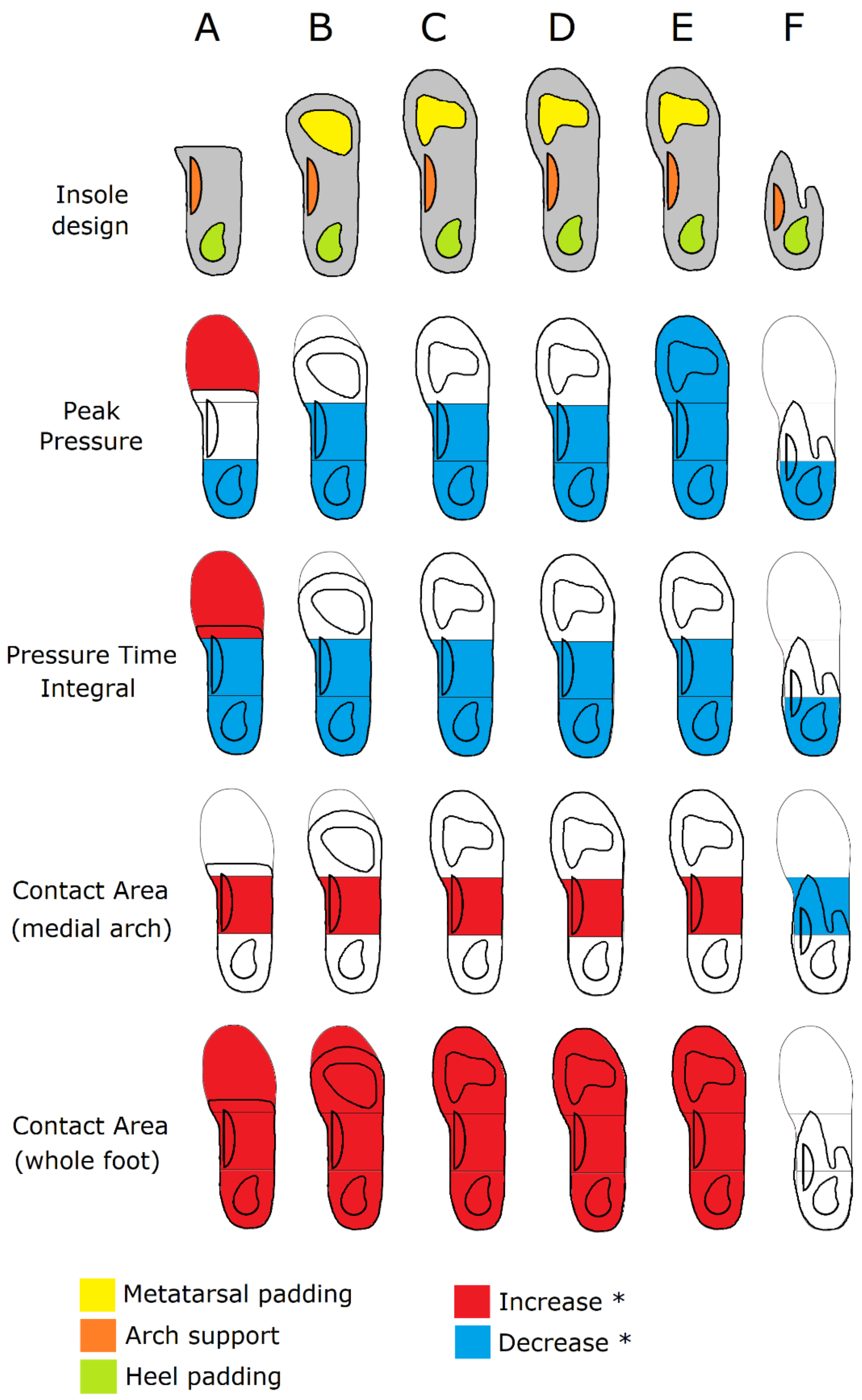

Figure 3. Summary of plantar pressure changes across the prefabricated orthotic insole range.

*The overall shape and design features of each insole are shown; metatarsal padding (yellow), arch support (orange) and heel padding (green). Peak Pressure (PP) and Pressure Time Integral (PTI) are displayed for ball of foot, medial arch and heel regions. Contact area (CA) was tested at the medial arch and whole foot regions only. * Increases (red) or decreases (blue) are shown for each parameter when statistical significance was observed for one or both feet, for each insole in the range (n = 23). All insoles with heel padding decreased PP and PTI at the heel region. All insoles with arch support (full- and ¾-length insoles) increased CA at the medial arch and whole foot, reduced PTI at the medial arch, and reduced PP at the medial arch (with the exception of insole A).*

Table 2: Change in joint orientation as a result of each insole compared with shoe alone.

Parameter	Left / Right / Not applicable (L/R/NA) (mean, 95% CI)	Orthotic insole					
		A (n=24)	B (n=24)	C (n=23)	D (n=23)	E (n=23)	F (n=24)
Rearfoot angle at contact (^{0})	L	-0.43 (-3.83, 2.97)	0.20 (-2.17, 2.58)	0.30 (-1.85, 2.46)	0.07 (-2.14, 2.27)	0.34 (-2.00, 2.68)	0.12 (-1.47, 1.71)
	R	-0.15 (-2.69, 2.40)	0.51 (-1.86, 2.88)	0.58 (-1.41, 2.57)	0.46 (-1.76, 2.68)	0.90 (-1.39, 3.18)	0.26 (-1.81, 2.33)
Maximum rearfoot angle (^{0})	L	-0.56 (-4.07, 2.94)	0.36 (-2.99, 3.71)	0.15 (-2.78, 3.07)	-0.21 (-2.87, 2.44)	0.50 (-2.43, 3.44)	-0.02 (-2.22, 2.18)
	R	0.13 (-2.55, 2.81)	-0.03 (-2.66, 2.59)	-0.35 (-2.42, 1.72)	0.07 (-2.27, 2.41)	0.21 (-2.01, 2.43)	-0.50 (-2.92, 1.93)
Rearfoot excursion (^{0})	L	-0.10 (-1.13, 0.93)	-0.05 (-1.14, 1.03)	-0.16 (-1.31, 0.99)	-0.27 (-1.3, 0.77)	-0.37 (-1.41, 0.66)	-0.37 (-1.34, 0.60)
	R	-0.06 (-1.28, 1.15)	0.29 (-1.02, 1.60)	0.93 (-0.23, 2.09)	0.30 (-1.58, 2.18)	0.91 (-0.67, 2.49)	0.76 (-0.54, 2.06)
Hip adduction (^{0})	L	0.47 (-0.19, 1.13)	-0.07 (-0.74, 0.59)	-0.43 (-1.22, 0.36)	0.44 (-0.27, 1.14)	0.24 (-0.20, 0.66)	-0.74 (-1.72, 0.25)
	R	-0.42 (-1.29, 0.45)	0.39 (-0.65, 1.42)	0.03 (-0.79, 0.85)	-0.96 (-2.14, 0.22)	-0.16 (-0.82, 0.50)	-0.78 (-1.52, -0.03)*****
Pelvic tilt (^{0})	NA	0.09 (-1.19, 1.37)	-0.10 (-0.59, 0.39)	-0.05 (-0.64, 0.53)	-0.00 (-0.65, 0.64)	-0.08 (-0.71, 0.54)	-0.08 (-0.75, 0.59)
Pelvic obliquity (^{0})	NA	3.49 (-4.24, 11.22)	0.45 (-0.07, 0.97)	0.18 (-0.27, 0.63)	0.33 (-0.36, 1.02)	0.10 (-0.36, 0.57)	1.08 (0.09, 2.07)*****

** Result with insole was statistically significantly different from standard shoe alone (statistical significance was present when the 95% confidence interval did not include zero). n=23 (Insoles C, D & E), n=24 (Insoles A, B & F).*

Table 3. Change in kinetics as a result of each insole compared with shoe alone.

Parameter	Left / Right (L/R) (mean, 95% CI)	Orthotic insole					
		A (n=24)	B (n=24)	C (n=23)	D (n=23)	E (n=23)	F (n=24)
Vertical force (BW)	L	0.00 (-0.01, 0.01)	0.01 (-0.01, 0.02)	0.00 (-0.02, 0.02)	0.01 (-0.01, 0.02)	-0.00 (-0.02, 0.01)	0.00 (-0.01, 0.02)
	R	0.00 (-0.01, 0.02)	-0.00 (-0.02, 0.02)	-0.00 (-0.02, 0.02)	-0.01 (-0.03, 0.01)	-0.01 (-0.03, 0.01)	-0.00 (-0.02, 0.02)
Vertical impulse (BW.s)	L	0.00 (-0.01, 0.02)	-0.00 (-0.01, 0.00)	-0.00 (-0.01, 0.00)	-0.00 (-0.01, 0.00)	-0.00 (-0.01, 0.00)	0.00 (-0.00, 0.01)
	R	0.00 (-0.01, 0.01)	-0.01 (-0.01, 0.00)	-0.01 (-0.02, 0.00)	-0.00 (-0.01, 0.00)	-0.00 (-0.01, 0.01)	0.00 (-0.00, 0.01)
Ankle inversion moment (BW.m)	L	0.02 (0.01, 0.04)*	0.01 (-0.13, 0.36)	0.01 (-0.01, 0.02)	0.01 (-0.01, 0.02)	0.02 (0.00, 0.04)*	0.01 (0.00, 0.03)*
	R	0.00 (-0.02, 0.03)	-0.01 (-0.04, 0.03)	0.00 (-0.04, 0.04)	0.01 (-0.02, 0.04)	0.00 (-0.02, 0.02)	0.00 (-0.01, 0.02)
Ankle eversion moment (BW.m)	L	0.03 (-0.01, 0.06)	0.01 (-0.03, 0.05)	0.03 (0.01, 0.06)*	0.03 (-0.00, 0.06)	0.07 (0.04, 0.09)*	0.02 (-0.01, 0.04)
	R	0.03 (0.01, 0.04)*	-0.01 (-0.02, 0.01)	0.01 (-0.00, 0.03)	0.02 (0.01, 0.04)*	0.02 (0.01, 0.04)*	0.02 (0.00, 0.03)*
Knee adduction moment (BW.m)	L	0.04 (0.01, 0.07)*	0.03 (-0.00, 0.06)	0.03 (0.01, 0.05)*	0.03 (0.01, 0.05)*	0.05 (0.02, 0.08)*	0.04 (0.02, 0.06)*
	R	0.04 (0.02, 0.05)*	-0.00 (-0.02, 0.01)	0.00 (-0.02, 0.03)	0.01 (-0.01, 0.03)	0.02 (-0.01, 0.04)	0.02 (0.01, 0.03)*
Hip adduction moment (BW.m)	L	0.04 (0.00, 0.08)*	0.05 (0.01, 0.09)*	0.03 (-0.01, 0.07)	0.03 (-0.00, 0.07)	0.03 (-0.00, 0.07)	0.02 (-0.02, 0.06)
	R	0.03 (-0.01, 0.07)	0.03 (0.00, 0.06)*	-0.00 (-0.04, 0.03)	0.01 (-0.03, 0.04)	0.03 (-0.01, 0.06)	0.01 (-0.02, 0.03)
Hip abduction moment (BW.m)	L	0.08 (-0.07, 0.23)	0.09 (-0.06, 0.24)	0.07 (-0.08, 0.23)	0.08 (-0.09, 0.24)	0.07 (-0.08, 0.21)	0.07 (-0.09, 0.22)
	R	0.01 (-0.01, 0.03)	0.00 (-0.01, 0.01)	0.01 (-0.00, 0.02)	0.01 (-0.01, 0.02)	0.00 (-0.02, 0.02)	0.00 (-0.01, 0.02)

*BW = body weight. * Result with insole was statistically significantly ($p<0.05$) different from standard shoe alone (statistical significance was present when the 95% confidence interval did not include zero). n=23 (Insoles C, D & E), n=24 (Insoles A, B & F).*

Discussion:

This novel comparative study contributes to our understanding of two key aspects of prefabricated insole use; mode-of-action and intended population. Direct comparison of six different insole designs allowed us to evaluate the impact of a range of geometric features and material properties on plantar pressure and gait – parameters that are generally reported for a single device design per investigation. Furthermore, in a field where most biomechanic investigations include diagnosed pain populations, our study provides data on the effects of prefabricated orthotic insoles in a healthy population. This is especially relevant as prefabricated insoles are commonly purchased over-the-counter by an undiagnosed population who self-select their device.

The findings show that, for each of the 6 prefabricated insoles in the range, although there was no consistent evidence of significant alteration of gait mechanics when compared with the control shoe, there were significant changes in plantar pressure distribution associated with specific orthotic design features.

Plantar pressure redistribution

Heel cups and padding

At the heel area, PP and PTI were statistically significantly reduced (in one or both feet) by all insoles in this range; all insoles had heel cups and heel padding (with the exception of Insole B which had heel padding only). These findings are consistent with data from similar studies which also report reductions in pressure at the heel region as a result of orthotic insoles that aim to mitigate the repetitive forces and MSK stresses generated at the heel strike during walking [5, 41, 42].

Arch support

This study found a statistically significant increase in CA at the medial arch region for all full- and ¾ - length insoles in the range (A-E), due to the raised geometry of their arch support making contact in previously non-weightbearing areas of the midfoot. A significant increase in CA was also observed for the whole foot for these insoles. Each of these insoles also significantly reduced PTI at the medial arch and insoles B-E significantly reduced PP in this region. Interestingly, Insole A did not affect PP at the medial arch, however this insole had the highest arch support of the range, suggesting that compression of the EVA foam during gait was not enough to reduce PP at this arch height. This would align with data from harder, less shock-absorbing custom orthotic insoles obtained from healthcare professionals, which have been shown to increase in PP under the metatarsal bones and lateral foot [5], and for contoured foot orthoses that increase CA and also increase PP under the medial midfoot [42]. Based on the medial arch CA, PP and PTI data generated during this study, one advantage of this range of prefabricated insoles is that they provide structural support at the arch without the increase in PP often seen with harder orthosis; in fact this range statistically reduced PP and PTI at the arch, which could potentially have beneficial effects on user comfort and may improve insole compliance.

In contrast, Insole F (the heel cup design) produced a significant decrease in CA at the medial arch region, presumably due to the increased height provided by its heel raise and its more minimal arch support. Furthermore, Insole F was the only device in the range not to significantly increase CA across the whole of the foot, which was expected as this device was designed to make contact with a much smaller plantar surface area. For this insole, PP at the medial arch was reduced (although this was not statistically significant), possibly due to the pressure redistribution effects of a heel raise.

Metatarsal padding

The insoles in this range with softer PU foam pads incorporated into the ball of foot region (Insoles B-E) produced a consistent reduction in PP at the forefoot, although this reduction was statistically significant for Insole E only. The assumption that metatarsal padding in the forefoot region would have a beneficial impact on plantar pressure in this region does not consider the pressure redistribution effects of the midfoot and heel sections of the insole. For example, Insole A has the highest heel height of the range in relation to the forefoot as it is designed to be placed under the arch and heel only; in this case, we observed a statistically significant increase in both PP and PTI at the ball of foot region, presumably due to the pressure redistribution effects of heel height. Similarly, Van Lunen et al., [35] reported a 30% increase in PP under the medial forefoot reported when walking or jogging whilst wearing an orthotic insole incorporating a 15-mm high heel raise that the authors describe as “a cross between a sturdy heel cup and ¾-length orthosis”; very similar in design to insole A of this study. Therefore, taking the height of the heel cup into account may help to explain why the reductions in PP at the forefoot regions that we observed for insoles with metatarsal padding did not reach statistical significance – the potential increase in PP caused by the redistribution effects of the heel cup was mitigated by the metatarsal padding.

Although orthoses specifically used to control metatarsalgia symptoms aim to lower peak plantar pressures in the forefoot [2, 43], orthotic studies have demonstrated both significant reductions [34, 5] and contrasting significant increases [8, 35] in pressure under the forefoot. Our findings suggest that it is important to consider the variation in orthotic device design, and how this may translate to differences in overall plantar pressure redistribution, especially for PP at the forefoot region.

Plantar pressure redistribution summary

The shared design features of the prefabricated insoles in this investigation contributed to the mode of action of plantar pressure redistribution via a combination of: 1) the geometry of each insole in the range making contact in areas not previously weight bearing (e.g. heel cup embracing the sides of the heel and/or arch support compressing under the arch), and 2) the material properties in areas of the foot that do bear load (e.g. varying density of materials at different regions including forefoot, arch and heel areas). In general, ¾- and full-length insoles with heel cups and medial arch geometries consistently increased CA at the medial arch region and reduced both PP and PTI at medial arch and heel regions (as summarised in Figure 3). Reductions in PP and PTI likely occurred as a result of the shock absorbing properties of the EVA and PU foam materials used in the range, particularly at the heel region. These findings were demonstrated across this insole range, in a similar manner to the pressure redistribution patterns described by Stolwijk et al., [5] for different foot complaints and arch heights when comparing a range of insoles.

Alteration of gait

On the whole, the insoles included in this investigation did not impact gait; there was an absence of consistent statistically significant changes in kinematic and kinetic data for the majority of insole types. Where statistically significant changes in kinetics were observed these were always increases, however the variability in parameters between insole designs and the lack of consistency between left and right sides of the body do not allow for meaningful conclusions and more evidence is needed to determine the impact of insole design features on kinetics. Of the few published studies that compare the biomechanic effects of custom-made and prefabricated orthotics, the majority do not demonstrate consistent effects or convincing evidence that prefabricated orthotics influence gait significantly differently than custom orthotics [7, 9, 36, 37]. Interestingly, where prefabricated and full-contact custom orthotic insoles have been shown to provide immediate improvements in gait, only the custom orthoses were able to maintain this for 4 weeks [37].

Traditional orthotics aim to control excessive or abnormal motion of the foot [8], as per the *kinetic paradigm* which states that orthotic insoles are generally required to significantly affect gait in order to be efficacious [5]. However, their precise effect on gait mechanics (and how this translate to clinical benefit), particularly for prefabricated insoles, is yet to be fully determined. For the general population self-selecting commercially available prefabricated orthotic insoles, it may be advantageous that these devices do not seem to modify gait; the lack of significant gait alteration observed in the current study (of a healthy population displaying mild foot pronation) could therefore be perceived as a beneficial feature of prefabricated insoles designed to redistribute plantar pressure, without detrimentally affecting gait.

Prefabricated orthotic insoles: intended population

Prefabricated orthotic insoles represent a low-cost, easily accessible treatment option for MSK pain, particularly mild or moderate pain that does not warrant intervention from a healthcare professional. In a healthy population, prefabricated insoles offer a means to alleviate or prevent mechanical stresses and plantar pressure associated with prolonged walking or standing, known to contribute to overuse injuries and lower body MSK pain [11, 16, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32]. The value of performing biomechanical testing on a range of prefabricated orthotic insoles in a healthy population, such as this study, is that the general population is often not represented in the literature, despite being the primary intended population for such self-select devices; the majority of data to support their mode of action comes from clinical studies that include patients with diagnosed pain conditions and/or gait abnormalities.

Prefabricated orthotic insole design features

This study directly compared a range of six prefabricated insoles which differed in their geometries and material properties, yet shared common orthotic design features (arch support, heel cup and metatarsal padding). We conclude that the shared design features of this range were able to elicit comparable changes in plantar pressure at specific regions of the foot. Although our data suggest that similar prefabricated orthotic insole designs could have similar effects on plantar pressure redistribution, it is difficult to generalise our findings to the huge range of commercially available prefabricated orthotic designs. Further comparative studies would be useful in determining the effects of specific geometric variations on plantar pressure, both in healthy populations and in those with diagnosed musculoskeletal lower body or foot pain.

Study limitations

One limitation of this study was that the investigation was conducted on a single day; long-term adaptation to orthoses was not investigated. Furthermore, as this study was conducted on healthy participants, there was no evaluation of the extent to which the biomechanic effects provided by these insoles may translate to pain relief. To investigate efficacy, a subsequent study of 4 of the insoles in this range has been conducted to evaluate their tolerability and impact on MSK pain in a population who spent most of their working day on their feet (data on file – Reckitt Health, UK).

This study presented statistical outcomes for left and right feet separately. Interpretations focused on evidence where both left and right showed statistically significant effects, since this offered the most robust evidence of effect. However, in cases where unilateral changes were observed, often the non-significant side showed evidence of change in the same direction as the side showing significant effects and was close to statistical significance. Lack of statistical significance across both feet is therefore not considered evidence of a nil effect.

Conclusions

By directly comparing 6 orthotic insole designs, this investigation has aided in further understanding the mode of action of prefabricated insoles and their impact on biomechanics in a healthy population. The insoles in this study reduced plantar pressure at key regions of the foot, based on geometric design features common to prefabricated insoles, yet there was no evidence that gait mechanics were impacted; an important consideration for the general population, for which unintended alteration of gait could be detrimental. Commercially available prefabricated insoles represent an easily accessible means of reducing lower body musculoskeletal stress and could be especially beneficial to those who spend prolonged periods of time on their feet.

List of Abbreviations

BMI = Body Mass Index
BOF = Ball of foot
CA = Contact Area
EVA = Ethylene Vinyl Acetate
FPI = Foot Posture Index
ITT = Intention to Treat
MSK = Musculoskeletal
PP = Peak Pressure
PTI = Pressure Time Integral
PU = Polyurethane
SD = Standard Deviation
TPE = Thermo Plastic Elastomer
TPU = Thermoplastic polyurethane

Declarations

Ethics approval and consent to participate

This study was conducted in compliance with the Declaration of Helsinki, International Council for Harmonisation Good Clinical Practice (GCP) and International Standard ISO 14155:2011. Written informed consent was obtained from all participants. The Federal Agency for Medicines and Health Products (FAMHP) and the University of Liege Ethics committee granted approval for this study.

Consent for publication

Not applicable.

Availability of data and materials

The data that support the findings of this study are available from Scholl's Wellness Company but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Scholl's Wellness Company.

Competing interests

SC, JH, CB, CH, CG and AS are employees of Reckitt Health and TH is an employee of Scholl's Wellness Company; manufacturers of orthotic insoles.

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Authors' contributions

JH, CB, CG, TH and CH contributed to the conception and design of the study. JFK and CSchwartz collected the study data. AS provided statistical analysis. CStarbuck provided insight regarding the methodology and interpretation of pressure and gait data. SC was a major contributor in writing the manuscript. All authors read and approved the final manuscript.

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Martin Haines contributed to the design and conduct of the study.

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