Published in : Prosthetics and Orthotics International (2024), vol. 48, no. 4, pp. 474-480
DOI: 10.1097/PXR.0000000000000292
Status : Postprint (Author's version)

EFFECTS OF A RANGE OF 6 PREFABRICATED ORTHOTIC INSOLE DESIGNS ON PLANTAR PRESSURE IN A HEALTHY POPULATION:

A RANDOMIZED, OPEN-LABEL CROSSOVER INVESTIGATION

Stephanie Cooper[1] , Jennifer Hanning[1], Carol Hegarty[1], Christian Generalis[1], Adam Smith[1], Tanya Hall[2], Chelsea Starbuck[3], Jean François Kaux[4], Cédric Schwartz[4] and Carolyn Buckley[1]

[1]Reckitt Health Ltd., Hull, United Kingdom
[2]Scholl's Wellness Company Ltd., Hull, United Kingdom
[3]Applied Sports, Technology, Exercise, and Medicine Research Centre, Faculty of Science and Engineering, Swansea University, Swansea, United Kingdom
[4]University Hospital of Liège, Liège, Belgium
Corresponding author: Stephanie Cooper, Reckitt Health Ltd., Dansom Lane, Hull HU8 7DS, United Kingdom. Email: stephanie.cooper@reckitt.com

Abstract

Background: Prefabricated orthotic insoles are widely commercially available for self-selection to treat foot and lower-body musculoskeletal pain, without requiring advice from health care professionals. 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 are poorly understood.

Objective: This investigation aimed to evaluate and directly compare the effects of a range of 6 different commercially available prefabricated orthotic insole designs on plantar pressure in healthy individuals.

Methods: This was a single-center, randomized, open-label, crossover investigation. In-shoe dynamic pressure (F-scan) was 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 insole was determined by the statistical significance of changes from baseline measurements (standard shoe alone).

Results: Insoles with heel cups and medial arch geometries consistently increased contact area at medial arch and whole-foot regions and reduced both plantar peak pressure (PP) and pressure time integral 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. Prefabricated orthotic insoles 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, plantar pressure, pressure redistribution

Published in : Prosthetics and Orthotics International (2024), vol. 48, no. 4, pp. 474-480
DOI: 10.1097/PXR.0000000000000292
Status : Postprint (Author's version)

Background

Orthotic insoles: custom vs. prefabricated

Many types of foot orthoses are available to treat foot and lower-body musculoskeletal (MSK) pain, ranging in complexity from generic "off-the-shelf" heel pads to custom ("custom-made") foot orthoses. Differentiating between this broad variation can be confusing as differences in 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.[1-3] As such, orthotic insoles are commonly separated based on their method of manufacture: custom or prefabricated.

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

Efficacy of orthotic insoles

A growing body of evidence suggests that prefabricated orthotics are effective in reducing many lower-body MSK pains, including foot, heel, knee, leg, and lower-back pain,[7-15] with improvements in both pain and function comparable with that of traditional customorthotics.[6,7,16] The efficacy of orthotic insoles has also been clearly demonstrated in populations who spend significant periods of time "on their feet," with studies reporting reduced MSK pain in police officers,[17] soldiers,[18] naval recruits,[19] nurses,[20] factory workers,[12] and others whose jobs involve prolonged standing[8,21-23] or long-distance walking.[24] Orthotics are proposed to alleviate lower-limb mechanical stresses associated with prolonged walking and standing—recognized as major contributors to overuse injuries and lower-body MSK pain.[25-27] As such, the benefits of orthotic insole use span far wider than simply those with diagnosed pain conditions.

Design features and material properties of orthotic insoles

Custom orthotic insoles are inherently variable by design, yet frequently possess very similar shapes and can produce comparable 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 recognize that although orthotic insoles may be termed "custom" or "prefabricated", significant overlap exists in terms of design features—both use traditional orthotic design features commonly used in clinical practice: midfoot (arch) support, heel cups, heel raises, metatarsal cushioning, and posting or wedging.

Published in : Prosthetics and Orthotics International (2024), vol. 48, no. 4, pp. 474-480
DOI: 10.1097/PXR.0000000000000292
Status : Postprint (Author's version)

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,[28] whereas semirigid orthoses have a higher hardness/firmness and are designed to provide structure and support to the foot.[3,29] It could therefore be argued that the design features and physical attributes of orthotic insoles should be considered above their method of manufacture. Indeed, the overarching mode of action of orthotic insoles is reliant on these common characteristics, used in varying combinations. This may help to explain why recent studies have reported comparable efficacy between custom and prefabricated designs.[6,7,16]

The mode of action of orthotic insoles

Despite the common and well-accepted clinical use of orthotic insoles to treat lower-body MSK pain, their physiological basis or mode of action is not yet well understood. Little comparative experimental data exist on the biomechanical impact of various orthotic designs, or indeed how these features translate to clinical success.[5] Meta-analysis of potential mechanisms of foot orthoses revealed 2 key paradigms: the shock 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 "normalize excess pronation and subsequent coupled movements in the lower body (eg internal tibial rotation)." Both paradigms, although separate, can simultaneously contribute to how orthotic insoles alleviate MSK pain; therefore, orthoses are usually prescribed with the aim of optimizing foot mechanics and function, and/or for providing cushioning and off-loading of foot structures.[28]

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 are variable and seemingly dependent on geometric design, with some studies reporting reduced peak plantar pressure in the forefoot[30] and others reporting increases in forefoot and midfoot plantar pressure.[29,31]

Summary and study objectives

Although prefabricated insoles are generally designed to replicate traditional orthotic design features, huge variation in their geometry and material properties exists, and there is a lack of evidence to demonstrate their impact on plantar pressure. 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, this investigation aimed to consecutively investigate and compare the impact of 6 different prefabricated orthotic insole designs on plantar pressure distribution in a population with normal foot posture.

Published in : Prosthetics and Orthotics International (2024), vol. 48, no. 4, pp. 474-480
DOI: 10.1097/PXR.0000000000000292
Status : Postprint (Author's version)

Methods

Participants

Twenty-four healthy male and female participants age 18–60 years, with a body mass index of 18.5–24.9 kg/m^2 and shoe size 4.5–11 (United Kingdom)/37–45 (European), were included. Informed consent, baseline demographic information, and relevant medical and medication history were obtained from all participants. A physical examination was performed and foot posture index (FPI-6)[32] was determined (FPI was calculated on a scale of 2 2 to 12 for each of the 6 clinical criteria, giving a final FPI score between 212 and 112); participants were included if they had a final FPI between 16 and 19, had no walking impairments, and could walk without distress.

Participants were excluded if they had leg-length discrepancy (.5 mm), peripheral vascular disease or sensory neuropathy, current or previous injury (within the past year), foot pain, or broken/irritated or damaged skin on their feet. Those who used orthotics (prescribed or self-administered), had consulted a health care professional for a gait-related or foot pain issue, or had a history of lower-limb surgery were also excluded.

Experimental protocol

This was a single-center, open-label, crossover 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 was investigated in 24 healthy subjects wearing neutral standard shoes in combination with 6 prefabricated orthotic insoles consecutively, in a randomized order, measured on a single day.

Standard shoe

The control was a standard unisex shoe (Converse All Star Ox [M7652C Optic White], Converse) worn with the manufacturer's insole removed (referred to as Device G or "standard shoe alone"); the standard shoe had no design features that reduced the effects of pronation.

Prefabricated orthotic insole range

A range of 6 prefabricated orthotic insoles (Scholl InBalance Pain Relief insoles, Scholl's Wellness Company, UK) was 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), thermoplastic elastomer, or thermoplastic PU, and incorporated design features such as arch support, heel cup, and heel and metatarsal pads (Table 1). Four of the insoles are commercially available, intended to be self-selected by an adult population experiencing mild MSK pain, and not intended to be used to treat severe pain, injury, or gait abnormalities.

Randomization

Subjects were randomized to a sequence that defined the order in which the insoles and standard shoe alone were to be tested. The sequence of allocation was based on a 7 X 7 Latin square design.

Published in : Prosthetics and Orthotics International (2024), vol. 48, no. 4, pp. 474-480
DOI: 10.1097/PXR.0000000000000292
Status : Postprint (Author's version)

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 and cut to fit the size and shape of the shoe by the investigator (a podiatrist). After each insole was fitted, subjects walked for approximately 20 m, and the investigator and the subject each assessed the fit of the insole. If a problem was identified (ie, discomfort), the insole was refitted.

In-shoe dynamic pressure

In-shoe dynamic pressure measurements (F-Scan [wireless], Tekscan, Boston) were applied to both feet. Standard in-shoe sensors with 3.9 sensels per cm^2 were 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 50 Hz 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 familiarization period for each condition 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 3 walking trials, and a mean of the 3 was taken.

Statistical analysis

Continuous variables were summarized with means, standard deviations (SDs), and valid cases. Right foot and left foot were analyzed and summarized separately. 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.

Results

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 SD of10.82 years. Sex was balanced in the overall population (11 men and 13 women). All subjects were of White ethnic origin. The overall mean height was 1.7 m (SD = 0.09, range = 1.54–1.88 m), the mean body mass was 63.63 kg (SD = 10.12, range = 44.0–88.0 kg), the mean body mass index was 22.03 kg/m^2 (SD = 2.02, range = 18.6–24.9 kg/m^2), and all subjects were within the required FPI range of +6 to +9 (mean = +6.6, SD = 0.93).

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 summarized in Figure 3; variability between insoles and anatomical areas of interest (BOF, medial arch, and heel) was observed.

Published in : Prosthetics and Orthotics International (2024), vol. 48, no. 4, pp. 474-480
DOI: 10.1097/PXR.0000000000000292
Status : Postprint (Author's version)

Figure 1. The range of 6 prefabricated orthotic insoles (Scholl In-Balance 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 and 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 BOF 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 BOF 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 BOF 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 BOF 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

Abbreviations: BOF, ball of foot; EVA, ethylene vinyl acetate; PU, polyurethane; TPE, thermoplastic elastomer; TPU, thermoplastic PU.

Force and pressure

Peak pressure—PP

PP was consistently reduced for the majority of insoles across the BOF, 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 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.

PTI

Pressure–time integral measurements were consistently reduced at the heel and medial arch regions (Figure 2 [panel 2]; Figure 3). 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).The most significant changes in the medial arch area were noted for insoles A–E; statistically significant decreases in PTI were observed for both feet.

Published in : Prosthetics and Orthotics International (2024), vol. 48, no. 4, pp. 474-480
DOI: 10.1097/PXR.0000000000000292
Status : Postprint (Author's version)

CA

Contact area 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).

Safety results

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

Discussion

Plantar pressure redistribution

Significant changes in plantar pressure distribution were associated with specific orthotic design features. In general, 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. These shared design features likely 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, and (2) the shock-absorbing properties of the EVA and PU foam materials in areas of the foot that do bear load, particularly at the heel region.

Heel cups and padding

At the heel area, PP and PTI were statistically significantly reduced 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 studies of similar orthotic insoles, which also report reductions in mean and peak pressure specifically at the heel region,[5,33,34] therefore supporting the concept that orthotic insoles mitigate the repetitive forces and MSK stresses generated at the heel region during walking.

Arch support

The statistically significant increase in CA at the medial arch region for all full- and ¾-length insoles in the range (A–E) was likely due to the raised geometry of their arch support making contact in previously non–weight-bearing areas of the midfoot. 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 health care professionals, which have been shown to increase in PP under the metatarsal bones and lateral foot,[5] and with contoured foot orthoses that increase CA and PP under the medial midfoot.[35] Unlike the increase in PP often seen with harder orthoses, the insoles in this study statistically reduced PP and PTI at the arch, suggesting a soft

Published in : Prosthetics and Orthotics International (2024), vol. 48, no. 4, pp. 474-480
DOI: 10.1097/PXR.0000000000000292
Status : Postprint (Author's version)

cushioning effect at the medial arch. Such devices could potentially have beneficial effects on user comfort and insole compliance.

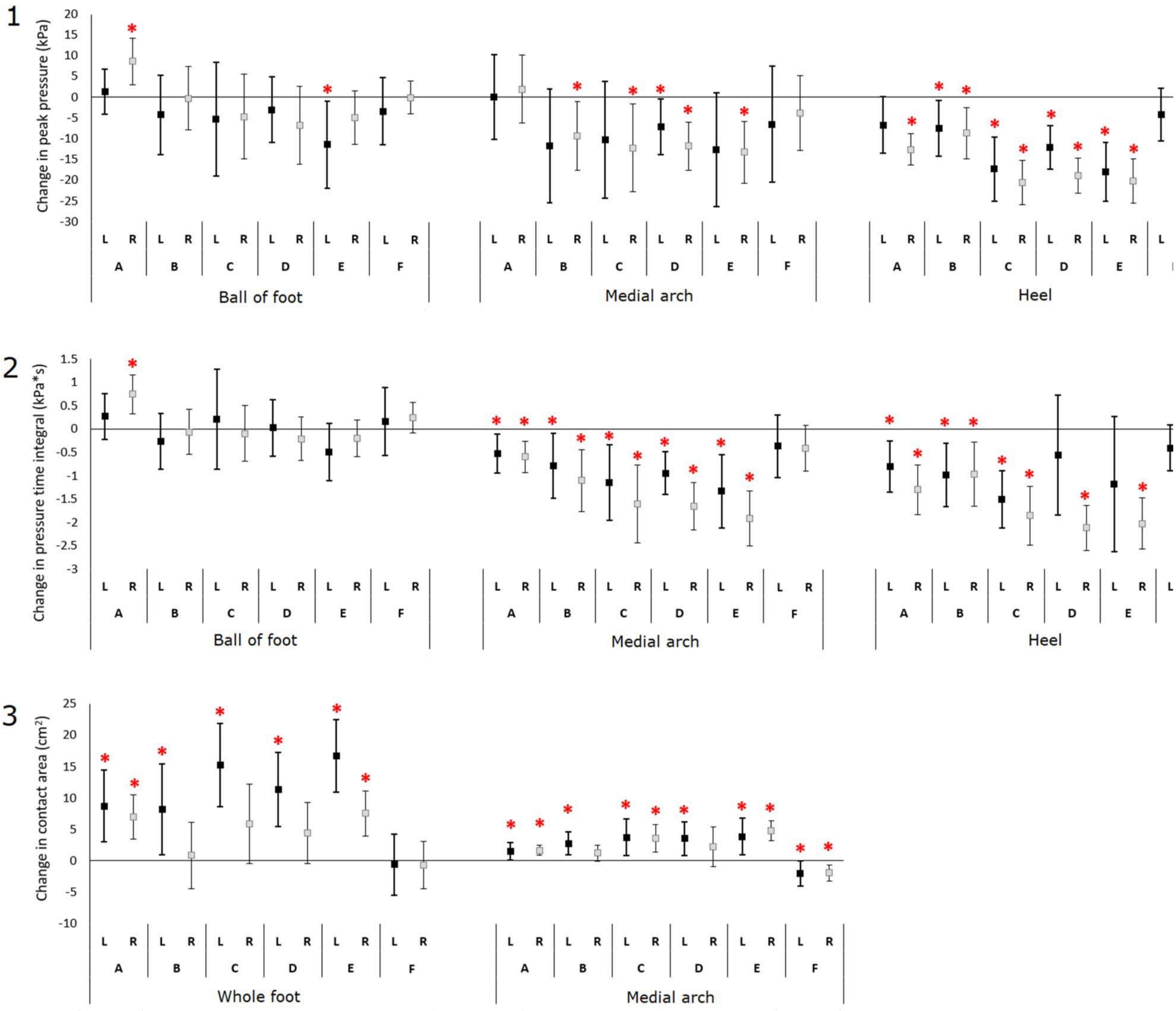

Figure 2. Force and pressure. Change in peak pressure (PP) (panel 1), PTI (panel 2), and CA (panel 3) from standard shoe alone; measured at BOF, medial arch, heel, and whole foot regions where indicated. Insoles indicated by letters A–F. L 5 left, R 5 right. Insoles A, B, and F, n523. Insoles C, D, and E, n 5 22. Data presented as mean and 95% confidence interval. Asterisks indicate statistical significance; present when the 95% confidence interval did not include zero. BOF, ball of foot; CA, contact area; PTI, pressure–time integral.

Metatarsal padding

The insoles in this range with softer PU foam pads incorporated into the BOF region (insoles B–E) produced a consistent trend of reduction in PP at the forefoot. The common assumption that metatarsal padding in the forefoot region has 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 BOF region, presumably because of the pressure redistribution effects of heel height. Similarly, Van Lunen et al[31] reported a 30% increase in PP under the medial forefoot reported when walking or jogging while wearing an orthotic insole incorporating a 15-mm high heel raise (very similar in design to insole A). 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,[2,34] orthotic studies have demonstrated both significant reductions[5,30] and contrasting significant increases[29,35] 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.

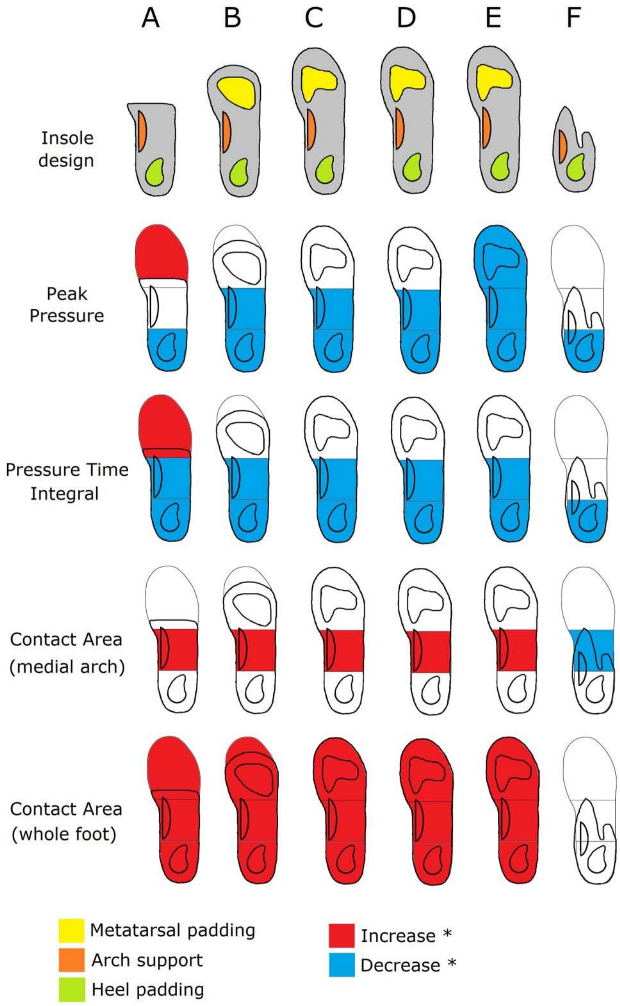

Figure 3. Summary of plantar pressure changes across the prefabricated orthotic insole range. The overall shape and design features of each insole are shown: metatarsal padding (yellow), arch support (orange), and heel padding (green). Peak pressure (PP) and PTI are displayed for BOF, medial arch, and heel regions. Contact area 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 5 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). BOF, ball of foot; CA, contact area; PTI, pressure–time integral.

Prefabricated orthotic insoles: intended population

Prefabricated orthotic insoles represent an easily accessible treatment option for those who experience mild or moderate MSK pain, yet do not seek intervention from a health care 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.[8,12,17-27] The value of performing biomechanical testing of prefabricated orthotic insoles in a healthy population, such as this study, is that the general population is not represented in the literature, despite being the primary intended population for such over-the-counter devices, designed for self-treatment of mild foot and lower-body pain in an otherwise healthy individual.

Study limitations

This study was conducted on a single day, therefore long-term adaptation to orthoses was not investigated. Furthermore, the extent to which the biomechanic effects provided by these insoles may translate to pain relief was not assessed as this study was conducted on healthy participants. A subsequent study of 4 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–XXXX).

Removal of the original Converse inlay of the control shoe is likely to have created a control condition with a high PP and PTI, more representative of walking on a harder surface than the typical use of such shoes (with inlays in place); we make no comparison between the insoles in this investigation and the Converse inlay.

Conclusions

This novel comparative study contributes to our understanding of both the mode of action of prefabricated insoles and their impact on a healthy population. The 6 prefabricated orthotic insole designs in this investigation significantly reduced plantar pressure at key regions of the foot (compared with a shoe with the inlay removed), based on geometric design features common to prefabricated insoles. Commercially available prefabricated insoles represent an easily accessible means of reducing lower-body musculoskeletal stress and could have clinical applications— further work is needed to investigate their clinical application and self-select application by the general public.

Author contributions

The authors disclosed the following roles as contributors to this article: J.H., C.B., C.G., T.H., and C.H. contributed to the conception and design of the study. J.F.K. and C.S. collected the study data. A.S. provided statistical analysis. C.S. provided insight regarding the methodology and interpretation of data. S.C. was a major contributor in writing the manuscript. All authors read and approved the final manuscript.

Ethics review and approval

The authors disclosed ethics review and approval for the research described in this article: 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

Published in : Prosthetics and Orthotics International (2024), vol. 48, no. 4, pp. 474-480
DOI: 10.1097/PXR.0000000000000292
Status : Postprint (Author's version)

from all participants. The Federal Agency for Medicines and Health Products (FAMHP) and the University of Liege Ethics committee granted approval for this study.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was funded by Reckitt Benckiser Healthcare Ltd, Hull, United Kingdom.

Declaration of conflicting interest

The authors disclosed the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: S.C., J.H., C.B., C.H., C.G., and A.S. are employees of Reckitt Health and T.H. is an employee of Scholl's Wellness Company, manufacturers of orthotic insoles.

References

1. Landorf KB, Keenan A and Herbert RD. Effectiveness of different types of foot orthoses for the treatment of plantar fasciitis. J Am Podiatr Med Assoc 2004;94:542–549.
2. Scherer PR, Waters LL, Choate CS, et al. Is there proof in the evidence-based literature that custom orthoses work? Podiatry Manag 2007;26: 109–122.
3. Mills K, Blanch P, Chapman AR, et al. Foot orthoses and gait: a systematic review and meta-analysis of literature pertaining to potential mechanisms. Br J Sports Med 2010;44:1035–1046.
4. Hawke F, Burns J, Radford JA, et al. Custom-made foot orthoses for the treatment of foot pain. Cochrane Database Syst Rev 2008;3:CD006801.
5. Stolwijk NM, Louwerens JW, Nienhuis B, et al. Plantar pressure with and without custom insoles in patients with common foot complaints. Foot Ankle Int 2011;32:57–65.
6. Luffy L, Grosel J, Thomas R, et al. Plantar fasciitis: A review of treatments. JAAPA 2018;31:20–24.
7. Wrobel JS, Fleischer AE, Crews RT, et al. A randomized controlled trial of custom foot orthoses for the treatment of plantar heel pain. J Am Podiatr Med Assoc 2015;105:281–294.
8. Basford JR and Smith MA. Shoe insoles in the workplace. Orthopedics 1988;11:285–288.
9. McRitchie M and Curran MJ. A randomised control trial for evaluating over the counter golf orthoses in alleviating pain in amateur golfers. Foot 2007;17:57–64.
10. Landsman A, Defronzo D, Anderson J, et al. Scientific assessment of over-the-counter foot orthoses to determine their effects on pain, balance, and foot deformities. J Am Podiatr Med Assoc 2009;99:206–215.
11. Mills K, Blanch P, Dev P, et al. A randomised control trial of short term efficacy of in-shoe foot orthoses compared with a wait and see policy for anterior knee pain and the role of foot mobility. Br J Sports Med 2012;46: 247–252.
12. Jefferson JR. The effect of cushioning insoles on back and lower extremity pain in an industrial setting. Workplace Health Saf 2013;61:451–457.
13. Cambron JA, Dexheimer JM, Duarte M, et al. Shoe Orthotics for the Treatment of Chronic Low Back Pain: A Randomized Controlled Trial. Arch Phys Med Rehabil 2017;98:1752–1762.
14. Sadler S, Spink M, Cassidy S, et al. Prefabricated foot orthoses compared to a placebo intervention for the treatment of chronic nonspecific low back pain: a study protocol for a randomised controlled trial. J Foot Ankle Res 2018;11:56.

15. Collins N, Crossley K, Beller E, et al. Foot orthoses and physiotherapy in the treatment of patellofemoral pain syndrome: randomised clinical trial. Br J Sports Med 2009;43:163–168.
16. Schuitema D, Greve C, Postema K, et al. Effectiveness of Mechanical Treatment for Plantar Fasciitis: A systematic review. J Sport Rehabil 2020; 29:657–674.
17. Sobel E, Levitz SJ, Caselli MA, et al. The effect of customized insoles on the reduction of postwork discomfort. J Am Podiatr Med Assoc 2001;91: 515–520.
18. Baxter ML, Baycroft C and Baxter GD. Lower limb injuries in soldiers: Feasibility of reduction through implementation of a novel orthotic screening protocol. Mil Med 2011;176:291–296.
19. Bonanno DR, Murley GS, Munteanu SE, et al. Effectiveness of foot orthoses for the prevention of lower limb overuse injuries in naval recruits: a randomised controlled trial. Br J Sports Med 2018;52:298–302.
20. Chiu MC and Wang MJ. Professional footwear evaluation for clinical nurses. Appl Ergon 2007;38:133–141.
21. King PM. A comparison of the effects of floor mats and shoe in-soles on standing fatigue. Appl Ergon 2002;33:477–484.
22. Waclawski ER, Beach J, Milne A, et al. Systematic review: plantar fasciitis and prolonged weight bearing. Occup Med 2015;65:97–106.
23. Speed G, Harris K and Keegel T. The effect of cushioning materials on musculoskeletal discomfort and fatigue during prolonged standing at work: A systematic review. Appl Ergon 2018;70:300–314.
24. Shabat S, Gefen T, Nyska M, et al. The effect of insoles on the incidence and severity of low back pain among workers whose job involves long-distance walking. Eur Spine J 2005;14:546–550.
25. Irvin RE. The origin and relief of common pain. J Back Musculoskelet Rehabil 1998;11:89–130.
26. Anderson J, Williams AE and Nester C. A narrative review of musculoskeletal problems of the lower extremity and back associated with the interface between occupational tasks, feet, footwear and flooring. Muscoskel Care 2017;15:304–315.
27. Kelly JL and Valier AR. The use of orthotic insoles to prevent lower limb overuse injuries: A critically appraised topic. J Sport Rehabil 2018;27: 591–595.
28. Tenten-Diepenmaat M, Dekker J, Heymans MW, et al. Systematic review on the comparative effectiveness of foot orthoses in patients with rheumatoid arthritis. J Foot Ankle Res 2019;12:32.
29. Hodgson B, Tis L, Cobb S, et al. The effect of 2 different custom-molded corrective orthotics on plantar pressure. J Sport Rehabil 2006;15:33–44.
30. Hodge MC, Bach TM and Carter GM. Orthotic management of plantar pressure and pain in rheumatoid arthritis. Clin Biomech1999;14:567–575.
31. Van Lunen B, Cortes N, Andrus T, et al. Immediate effects of a heel-pain orthosis and an augmented low-dye taping on plantar pressures and pain in subjects with plantar fasciitis. Clin J Sport Med 2011;21:474–479.
32. Keenan AM, Redmond A, Horton M, et al. The Foot Posture Index: Rasch analysis of a novel, foot specific outcome measure. Arch Phys Med Rehabil 2007;88:88–93.
33. Goske S, Erdemir A, Petre M, et al. Reduction of plantar heel pressures: Insole design using finite element analysis. J Biomech 2006;39:2363–2370.
34. Bonanno DR, Ledchumanasarma K, Landorf KB, et al. Effects of a contoured foot orthosis and flat insole on plantar pressure and tibial acceleration while walking in defence boots. Sci Rep 2019;9:1688.

35. Chang BC, Liu DH, Chang JL, et al. Plantar pressure analysis of accommodative insole in older people with metatarsalgia. Gait Posture 2014;39: 449–454.