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Title Page

In shoe pressure measurements during different motor tasks while wearing safety shoes: the effect of custom made insoles vs. prefabricated and off-the-shelf

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Highlights

- Safety shoes are heavy, rigid, uncomfortable and may cause foot problems
- Standard insoles in safety shoes are inadequate and do not account for foot types
- Fast walking in safety shoes results in high peak pressures
- Custom insoles based on foot shape allow for more even pressure distribution in safety-shoes

ABSTRACT

Health and safety regulations in many countries require workers at risk to wear safety shoes in a factory environment. These shoes are often heavy, rigid, and uncomfortable. Wearing safety shoes daily leads to foot problems, discomfort and fatigue, resulting also in the loss of numerous working days. Currently, knowledge of the biomechanical effects of insoles in safety shoes, during working activities, is very limited.

Seventeen workers from a metalworking factory were selected and clinically examined for any foot conditions. Workers feet were 3D scanned, with regards to their plantar view, and the images used to design 34 custom-insoles, based on foot and safety shoe models.

Three insoles were blind-tested by each worker: custom (CUS); prefabricated with the safety-shoe (PSS), and off-the-shelf (OTS). Foot-to-insole pressure distribution was measured in seven motor tasks replicating typical working activities: single and double-leg standing; weight lifting; stair ascending and descending; normal and fast walking.

Wearing CUS within safety shoes resulted in a greater uniform pressure distribution across plantar regions for most of the working activities. Peak pressure at the forefoot during normal walking was the lowest in the custom insole (CUS 275.9 ± 55.3 kPa; OTS 332.7 ± 75.5 kPa; PSS 304.5 ± 54.2 kPa). Normal and fast walking were found to be the most demanding activities in terms of peak pressure.

Wearing safety shoes results in high pedobarographic parameters in several foot regions. The use of custom insoles designed on the foot morphology helps decrease peak pressure and pressure-time integral compared to prefabricated featureless insoles.

Keywords: safety shoe; plantar pressure; custom insole; working activities; 3D foot scan

INTRODUCTION

Workplace injuries are often associated to residual disability and functional deficits, thus leading to the loss of working days and large economical and social costs. About 10% [1] and 25% [2] of all accidents occurring in the workplace is related, respectively, to the foot and ankle. According to the Italian Institute of Insurance for Professional Illness and Injuries, 700.000 work-related injuries are reported each year across a population of about 60 million people, and 15% of these affects the foot and ankle. In the United States, according to the Bureau of Labor Statistics, the foot and ankle are concerned with nearly 10% of the 12 million a-year workplace injuries. The foot is in fact an extremely fragile body region, whose lesions can be particularly disabling and hence require long recovery periods. The metatarsus and toes have been reported to be the most affected areas (34% of all injuries) [3], due to the frequent occurrence of heavy objects falling on the forefoot.

In order to limit the occurrence of foot injuries within the workplace, health and safety regulations recommend the use of safety footwear. Due to the variety of hazards across different workplaces, safety shoes are classified and recommended according to job-specific duties, as established in the European standards minimum requirements. Most safety footwear is equipped with hard toe caps which protect against impacts, protective uppers, puncture-resistant and anti-slip outsoles, and encapsulating backs. Although these features are designed to protect from serious accidents, they also inflict some discomfort to the worker's feet, with about 90% of workers reporting feet problems [4]. Maintaining a prolonged upright posture or moving heavy objects can lead to musculoskeletal disorders (e.g. fasciitis and tendonitis), lower leg edema, and fatigue due to reduced effectiveness of the venous-muscle pump mechanism [5]. Plantar pressure peak deviations, in particular heel and metatarsal heads overloading, are associated to muscular fatigue and may lead to lower limb stress reaction and fractures [6]. This is also due to the rigidity of some of the metal components comprising these shoes. Despite these critical issues, the relevant literature on this important topic is scarce [2, 4].

Current regulations are strict on the type, position and materials of the protective elements featuring standard safety shoes, but no clear recommendations have been established for the shoe footbed. The prefabricated insoles provided with safety shoes are often thin, with insufficient arch-support, and made of inadequate materials. However, feet morphology, and sometimes deformities, are unique to each person and shoe design can seldom take into account differences between the most typical foot types, such as flat or cavus foot. In-shoe pedobarography has long been used to study the effect of orthotics on plantar pressure distribution [7, 8], and the clinical implications of the foot-to-insole interface [9]. It has been shown that peak pressure can be reduced by adding cushioning elements to the footbed [10], thus providing early evidence of pressure relief when using appropriate orthotics. While off-the-shelf all-purpose

comfortable insoles may help to mitigate the inherent discomfort of wearing heavy and stiff safety shoes, these are available in a limited number of shapes and materials, and are hardly capable to fit specific foot types and safety shoes. Recent advancements in the 3D scanning technology, in association with CAD-CAM, is enhancing the design and production of custom insoles via subtractive or additive manufacturing [11, 12]. Custom insoles are prescribed as a non-invasive solution to deal with lower limb pathologies [13, 14], foot ailments and deformations [15, 16], and to improve sport performance [17]. These are usually more expensive than off-the-shelf insoles, since the design requires an in-depth examination with a podiatrist and additional measurements, but the user generally experiences a greater uniform pressure distribution, increased comfort, and less pain [18, 19]. However, the current literature on plantar pressure distribution in safety shoes is limited, and only one study has evaluated the plantar pressure distribution in barefoot standing to assess the effect of different insoles on the foot's health [20]. Moreover, in-shoe plantar pressure when wearing safety footwear has yet to be investigated in relation to different working activities. This information has the potential to provide recommendations and enhance the policies regulating the working activities of those required to wear safety shoes.

The purpose of this study was to assess the effect of safety shoes fitted with different insoles, on the resulting plantar pressure magnitude and distribution during common working activities.

A thorough clinical and functional evaluation was performed on subjects by physical examination, comfort scoring, and baropodometric measurements. The design of the subject- and footbed-specific custom insoles was obtained, for the first time, by integrating 3D foot morphological data and the shape of the safety shoes.

METHODS

Participants

A total of 40 workers of a metalworking factory (Bonfiglioli Riduttori, Italy) underwent clinical examination by an experienced physiatrist to identify morphological and functional characteristics, such as toes' alterations, soft tissue's pain, and plantar fasciitis. Workers found to have severe degenerative pathologies, systemic diseases (e.g. diabetes), and those with normal asymptomatic feet, were excluded for ethical reasons. In agreement with the specific criteria, and the metalworking company, 17 workers (6 women and 11 men, age 45.1 ± 5.2 years; BMI 26.7 ± 4.5 kg/m²; shoe size 42 ± 3 Euro) were chosen for this study. Fourteen of these workers reported to habitually wear plantar orthoses for foot ailments. Ethical

approval was granted by the Ethics Committee of “Istituto Ortopedico Rizzoli”, and informed consent was obtained from all participants.

Tested insoles

The workers wore safety shoes produced by the same footwear company (Base Protection, Italy) . The shoes feature a padded collar in the back, puncture-resistant outsole and a steel toe cap (figure 1.c). The safety shoes are fitted with thin, perforated, and featureless prefabricated insoles (PSS). The PSS was tested against a standard off-the-shelf insole (OTS) and a custom insole (CUS). The OTS is made in polyurethane combined with perforated thermoplastic material and covered by anti-slip surface; it features a latex heel pad, medial arch support, and a metatarsal bones pad insert (Figure 1.d).

Two CUS, made in EVA (ethylene-vinyl acetate), were independently designed on the morphology of the left and right foot of each subject, and according to the footbed of the safety shoes. The plantar view of each foot was 3D scanned with a system comprised of a commercial, laser-based foot scanner device (i-Qube, Delcam, UK) and an external frame holding an elastic membrane (Figure 1). The subject was asked to stand over the scanner and place the foot on the elastic membrane lying over the scanner top (Figure 1.a, 1.b). The tension in the membrane prevents the foot arch from flattening, replicating the plantar foot shape during dynamic activities, and allowing adjustment for specific corrections. CAD models of the shoes provided by the manufacturer aided the design of the CUS bottom to match exactly the shoe footbed. The CUS's were fabricated via subtractive-manufacturing from EVA blocks using a milling machine. As a final production quality check, the fit between each CUS and the corresponding foot and shoe was performed by visual inspection inside and outside the shoe.

Clinical and comfort evaluation

The Manchester Oxford Foot Questionnaire (MOxFAQ) was used to score the health status of the worker's feet [21]. The resulting overall comfort of the safety-shoe with insole compound was assessed, for each insole, via a 0 - 100 VAS-based questionnaire. A VAS score of 0 is associated to “Not comfortable at all” and 100 to “Most comfortable condition imaginable” [22]. Comfortable walking shoes owned by the workers, were used as a reference for comfort evaluation.

Pedobarography

Each worker wore safety shoes fitted with one of the three pairs of insoles, and walked through an ad-hoc “working-trial” replicating the most typical motor tasks performed during a working day: single-leg

standing upright posture; double-leg standing upright postures; normal walking; 4 kg weight lifting; fast walking; stair ascending, and stair descending. Blind randomized testing of the insoles was used for each worker. Plantar pressure at the foot-to-insole interface was measured using the 99-sensor Pedar insoles (Novel gmbh, Germany; pressure range 15-600 kPa; nominal accuracy 2.5-5 kPa) sampling at 50 Hz. PSS, OTS and CUS insoles were compared for the main pedobarographic parameters - i.e. maximum force (%Body Weight), peak pressure (kPa) and time-normalized pressure-time integral (PTI, kPa) - at rearfoot (0-30% insole length), midfoot (31-60% insole length), forefoot (61-100% insole length), and in the total foot [23]. Peak pressure was defined as the highest pressure recorded by any sensor in a region of interest, whereas normalized PTI was defined as the integral of peak pressure over the time of contact with the plantar region normalized to the stance duration. The latter was used to allow comparisons of PTI between motor tasks with differing durations. Since the CUS were individually designed and manufactured for each foot of each worker, left and right foot pressure samples were considered independent measurements.

Six steps (3 left, 3 right) during normal walking and 4 steps (2 left, 2 right) during fast walking were recorded and processed for each worker. During weight lifting each worker was asked to bend the knees while maintaining the back and spine as straight as possible; 8 s were recorded to include a full weight-lift and weight-drop cycle. A total of 3 steps were recorded for each worker during stair ascending/descending. Therefore, for each insole group, 34 pressure measurements were recorded and analyzed in weight lifting and in the two static postures (17 workers * 2 measurements), 51 steps in stair ascending and stair descending (17 * 3 steps), 68 steps in fast walking (17 * 4 steps), and 102 steps in normal walking (17 * 6 steps). Analysis of the regional pedobarographic parameters for each motor task was performed using an ad-hoc software written in Matlab (The MathWorks, Inc.) [24].

For each task, a non-parametric paired Friedman's test with a Bonferroni correction was used to assess the statistical differences in the pedobarographic parameters at each plantar region between the three insole groups ($\alpha=0.017$). In the CUS group only, Kruskal-Wallis was used to determine possible differences in total foot peak pressure between motor tasks. The Tukey-Kramer post-hoc test with a Bonferroni correction ($\alpha=0.0024$) was used to assess task-to-task statistical differences in peak pressure.

RESULTS

Clinical and comfort evaluation

The average MOxFQ score across all workers was 28.1 ± 11.9 (max 64 points). Some subjects claimed foot pain and social or functional limitations. The average (\pm SD) questionnaire sub-scores were the following: pain = 11.0 ± 4.3 (max 20 points, range 0-18); walking/standing = 10.3 ± 6.3 (max 28 points, range 0-21), and social interaction = 6.8 ± 3.7 (max 16 points, range 0-12). The VAS did not reveal any statistically

significant difference in comfort between the three insoles (PSS = 55.3 ± 24.6 ; OTS = 50.7 ± 24.8 ; CUS = 50.2 ± 22.7 ; $p > 0.05$).

Pedobarography

Normal walking cadence (steps/min) was 107 ± 6 in the PSS group, 107 ± 8 in the OTS, and 107 ± 7 in the CUS group. In fast walking this was respectively 122 ± 9 , 124 ± 11 , and 123 ± 9 . No statistical differences were found in cadence between the three groups during normal walking, fast walking, stair ascending and descending ($p > 0.05$).

Pedobarographic parameters in the CUS group were significantly different from the corresponding measurements in the PSS and OTS groups in almost all plantar regions and across all motor tasks (Table 1), as shown in the following paragraphs.

Maximum force

At rearfoot, CUS showed the lowest force in normal walking. Moreover, CUS showed lower force than OTS in single-leg standing, and lower than PSS in fast walking (Table 1). In most motor tasks, at midfoot, CUS showed the largest force and PSS the lowest. No significant differences were detected between the three insoles at forefoot (Table 1).

Peak pressure

CUS resulted more effective in reducing peak pressure across most motor tasks at rearfoot and forefoot (Figure 2, Figure 3 and Table 1). At midfoot, peak pressure in the CUS group was larger than PSS in most motor tasks.

Time-normalized pressure-time integral (PTI)

In general, CUS showed the largest PTI at midfoot and the lowest at rearfoot and forefoot across most motor tasks (Table 1). PTI in the PSS group was lower than OTS only at forefoot in normal walking.

Influence of motor tasks on peak pressure

Figure 3 shows regional peak pressure distributions for each motor task in increasing order of peak pressure at total foot in the CUS group. Normal and fast walking were found to be the most demanding tasks, whereas single-leg and double-leg standing produced the lowest peak pressure ($p < 0.0024$, Table 2).

DISCUSSION

Despite the increasingly strict regulations on safety shoes quality, which promote to minimize injuries and loss of working days, and the increasing rate of foot and musculoskeletal ailments reported in factory workplace, very little has thus far been investigated to improve workers' comfort and to increase our understanding on the biomechanics of the foot inside safety shoes. Safety shoes have been tested for the properties of their materials and components [25], slip resistance [26], and comfort [19, 22]. The effects of custom insoles on different musculoskeletal diseases have also been extensively reported [13, 14, 16]. Only

one study has investigated the effects of different insoles on musculoskeletal health of workers and on plantar pressure, albeit only static barefoot measurements were considered [20]. Though some of the safety-shoe features designed to protect the foot cannot be modified, the foot-to-shoe interface can surely be ameliorated by employing custom insoles.

In this study, custom insoles in EVA designed and produced to match the shape of the foot plantar surface and the safety shoe, were compared to prefabricated insoles provided with the safety shoe, and to generic comfortable insoles. The right and left foot were analyzed separately; therefore two different custom insoles were designed and provided to each worker. Unlike traditional moulds obtained with foams, or digitally by 3D scanning the foot flat on the scanner top, the foot plantar surface was wrapped by an elastic membrane and 3D scanned (Figure 1.a). Tension in the membrane can be adjusted to apply elevation to the foot arches, thus allowing the digitization of the foot plantar surface in a geometrical configuration similar to that occurring during the stance phase of walking. In fact, when the foot is laid flat on the scanner top, the foot arches flatten without resistance and the resulting static 3D image is different from the “dynamic” foot shape, thus potentially leading to an incorrect model for the corresponding insoles. Starting with a virtual 3D mould of the foot plantar surface, and a CAD model of the shoes, an optimal foot-to-insole and insole-to-shoe fitting was obtained. In addition, a cloud-based technological platform was used to share the relevant foot and shoe data between the orthopedic centre, the safety shoe manufacturer and the company designing the custom insoles. The procedure tested and exploited in this study for the personalization of plantar insoles appears promising, and potentially transferrable to any other shoe type.

To the best of the authors’ knowledge, in-shoe pedobarography was employed for the first time to assess the effect of different insoles on comfort and plantar pressure distribution in a population of workers wearing safety shoes. CUS insoles resulted in decreased peak pressure at rearfoot and forefoot when compared to PSS and OTS insoles. More force is sustained by the midfoot, which appears consistent with the larger foot-to-insole contact area provided by the CUS at the medial longitudinal arch. Nevertheless, even in the best combination of safety shoes fitting CUS, peak pressure during level walking at self-selected speed at midfoot and forefoot was respectively 88% and 27% higher than corresponding measurements recorded in very similar conditions (i.e. same instrumentation, analysis software, and laboratory/floor conditions) for comfortable shoes, albeit on a younger healthy population [24]. Time-normalized PTI in CUS was also lower than PSS at rearfoot and forefoot in double-leg standing. Decreasing the amount of pressure over time may be extremely beneficial to workers who stand for long periods in the assembly line, and could be correlated to increased comfort and reduced pain and tiredness [18, 19, 27]. Moreover, the study allowed identifying those common working activities which are more demanding in terms of peak pressure and PTI. While the two static postures of double-leg and single-leg standing were

the least demanding tasks in terms of peak pressure, they also showed quite large normalized PTI at rearfoot compared to other activities. Similar to what has been reported in previous studies [28, 29], normal and fast walking showed higher peak pressure than ascending and descending stair (Figures 2, 3 and Table 2).

No significant differences were found between the three insoles in perceived comfort. This may be due to the relative short time of the testing procedure, which has potentially prevented the workers from fully realizing the comfort of each insole configuration over an appropriate period of time. A follow-up evaluation would have allowed the workers also to better familiarize with the custom insoles in the work environment. However, with respect to the in-shoe pressure measurements, the different daily job activities performed by each worker may have produced inconsistent insole modifications, thus preventing the analysis of plantar pressure distribution in the same controlled testing conditions. It is worth highlighting that the custom insole design was based solely on the morphology of the foot plantar surface. The authors believe that the insole personalization could benefit from additional measurements, such as plantar pressure and foot kinematic parameters.

In general, the use of customized insoles within safety shoes proved to be an effective solution to reduce overloading and redistribute plantar pressure in workers' feet during typical working activities. However, because of the high incidence of lower limb work-related overuse pathologies, a further effort to enhance foot comfort should be sought by improving the design also of the safety shoes. Investigation of different ergonomic solutions of proven effectiveness, such as the implementation of unstable outsole [30] and appropriate textile components, could therefore be pursued.

All authors were fully involved in the study and preparation of the manuscript and the material within has not been and will not be submitted for publication elsewhere.

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REFERENCES

- [1] Conti SF, Silverman L. Epidemiology of foot and ankle injuries in the workplace. *Foot and ankle clinics*. 2002;7:273-90.
- [2] Werner RA, Gell N, Hartigan A, Wiggermann N, Keyserling WM. Risk factors for foot and ankle disorders among assembly plant workers. *American journal of industrial medicine*. 2010;53:1233-9.
- [3] Grimm DJ, Fallat L. Injuries of the foot and ankle in occupational medicine: a 1-year study. *The Journal of foot and ankle surgery : official publication of the American College of Foot and Ankle Surgeons*. 1999;38:102-8.
- [4] Marr SJ, Quine S. Shoe concerns and foot problems of wearers of safety footwear. *Occupational medicine*. 1993;43:73-7.
- [5] Chiu MC, Wang MJ. Professional footwear evaluation for clinical nurses. *Applied ergonomics*. 2007;38:133-41.
- [6] Bisiaux M, Moretto P. The effects of fatigue on plantar pressure distribution in walking. *Gait Posture*. 2008;28:693-8.
- [7] Burgess S, Jordan C, Bartlett R. The influence of a small insert, in the footbed of a shoe, upon plantar pressure distribution. *Clin Biomech (Bristol, Avon)*. 1997;12:S5-S6.
- [8] Hayda R, Tremaine MD, Tremaine K, Banco S, Teed K. Effect of metatarsal pads and their positioning: a quantitative assessment. *Foot & ankle international / American Orthopaedic Foot and Ankle Society [and] Swiss Foot and Ankle Society*. 1994;15:561-6.
- [9] Paton J, Bruce G, Jones R, Stenhouse E. Effectiveness of insoles used for the prevention of ulceration in the neuropathic diabetic foot: a systematic review. *Journal of diabetes and its complications*. 2011;25:52-62.
- [10] Basford JR, Smith MA. Shoe insoles in the workplace. *Orthopedics*. 1988;11:285-8.
- [11] Chung-Neng H, Ming-Yih L, Chong-Ching C. Computer-aided design and manufacturing of customized insoles. *IEEE computer graphics and applications*. 2011;31:74-9.
- [12] Ki SW, Leung AK, Li AN. Comparison of plantar pressure distribution patterns between foot orthoses provided by the CAD-CAM and foam impression methods. *Prosthetics and orthotics international*. 2008;32:356-62.
- [13] Rathleff MS, Richter C, Brushoj C, Bencke J, Bandholm T, Holmich P, et al. Custom-Made Foot Orthoses Decrease Medial Foot Loading During Drop Jump in Individuals With Patellofemoral Pain. *Clinical journal of sport medicine : official journal of the Canadian Academy of Sport Medicine*. 2015.
- [14] Skou ST, Hojgaard L, Simonsen OH. Customized foot insoles have a positive effect on pain, function, and quality of life in patients with medial knee osteoarthritis. *J Am Podiatr Med Assoc*. 2013;103:50-5.
- [15] Paton JS, Stenhouse EA, Bruce G, Zahra D, Jones RB. A comparison of customised and prefabricated insoles to reduce risk factors for neuropathic diabetic foot ulceration: a participant-blinded randomised controlled trial. *Journal of foot and ankle research*. 2012;5:31.
- [16] Postema K, Burm PE, Zande ME, Limbeek J. Primary metatarsalgia: the influence of a custom moulded insole and a rockerbar on plantar pressure. *Prosthetics and orthotics international*. 1998;22:35-44.
- [17] Lucas-Cuevas AG, Perez-Soriano P, Llana-Belloch S, Macian-Romero C, Sanchez-Zuriaga D. Effect of custom-made and prefabricated insoles on plantar loading parameters during running with and without fatigue. *Journal of sports sciences*. 2014;32:1712-21.
- [18] King PM. A comparison of the effects of floor mats and shoe in-soles on standing fatigue. *Applied ergonomics*. 2002;33:477-84.
- [19] Sobel E, Levitz SJ, Caselli MA, Christos PJ, Rosenblum J. The effect of customized insoles on the reduction of postwork discomfort. *J Am Podiatr Med Assoc*. 2001;91:515-20.
- [20] Almeida JS, Carvalho Filho G, Pastre CM, Padovani CR, Martins RA. Comparison of plantar pressure and musculoskeletal symptoms with the use of custom and prefabricated insoles in the work environment. *Brazilian Journal of Physical Therapy*. 2009;13:542-8.
- [21] Dawson J, Coffey J, Doll H, Lavis G, Cooke P, Herron M, et al. A patient-based questionnaire to assess outcomes of foot surgery: validation in the context of surgery for hallux valgus. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*. 2006;15:1211-22.

- [22] Mundermann A, Nigg BM, Stefanyshyn DJ, Humble RN. Development of a reliable method to assess footwear comfort during running. *Gait Posture*. 2002;16:38-45.
- [23] Carl HD, Pfander D, Swoboda B. Assessment of plantar pressure in forefoot relief shoes of different designs. *Foot Ankle Int*. 2006;27:117-20.
- [24] Caravaggi P, Giangrande A, Berti L, Lullini G, Leardini A. Pedobarographic and kinematic analysis in the functional evaluation of two post-operative forefoot offloading shoes. *Journal of foot and ankle research*. 2015;8:59.
- [25] Costa SL, Mendonça JP, Peixinho N. Numerical Simulation of Quasi-Static Compression Behavior of the Toe Cap Component for Safety Footwear. *International Journal of Computer Theory and Engineering*. 2014;6:285.
- [26] Gronqvist R, Hirvonen M, Tuusa A. Slipperiness of the shoe-floor interface: comparison of objective and subjective assessments. *Applied ergonomics*. 1993;24:258-62.
- [27] Messing K, Kilbom Å. Standing and very slow walking: foot pain-pressure threshold, subjective pain experience and work activity. *Applied ergonomics*. 2001;32:81-90.
- [28] Rao S, Carter S. Regional plantar pressure during walking, stair ascent and descent. *Gait Posture*. 2012;36:265-70.
- [29] Guldmond NA, Leffers P, Sanders AP, Schaper NC, Nieman F, Walenkamp GH. Daily-life activities and in-shoe forefoot plantar pressure in patients with diabetes. *Diabetes research and clinical practice*. 2007;77:203-9.
- [30] Karimi Z, Allahyari T, Azghani MR, Khalkhali H. Influence of unstable footwear on lower leg muscle activity, volume change and subjective discomfort during prolonged standing. *Applied ergonomics*. 2016;53 Pt A:95-102.

FIGURE legends

Figure 1

Procedure to design custom insoles from 3D scan of the foot plantar surface.

- The tension in the elastic membrane exerts a vertical force to the foot on the scanner top.
- Rendered images of feet plantar surface.
- The safety shoes worn during the tests.
- From top to bottom: prefabricated safety-shoe insoles (PSS); off-the-shelf insoles (OTS), and an exemplary custom (CUS) insole in EVA.

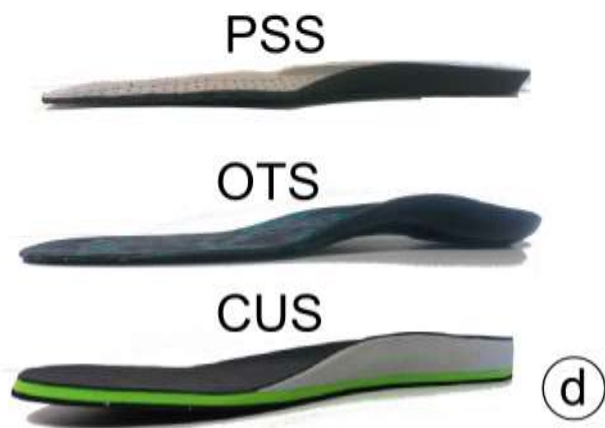
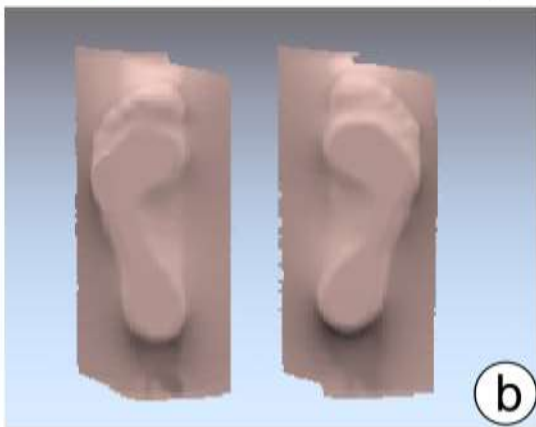


Figure 2

Top to bottom, in increasing order of peak pressure at total foot, color-maps of the mean peak pressure (kPa) at each sensor across all trials of each motor task, in the three insole groups.

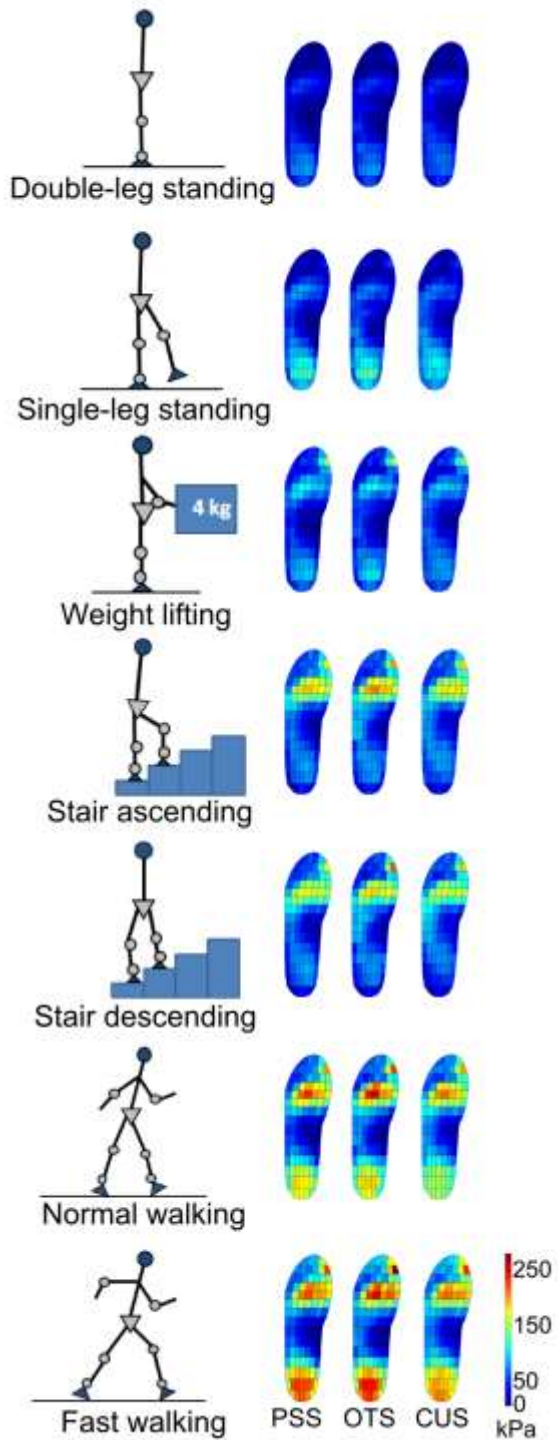


Figure 3

Left to right, in increasing order of peak pressure at total foot, peak pressure distribution (median, 25% and 75%) in the CUS group for each motor task at rearfoot, midfoot, forefoot, and in the total foot. The relevant statistics are reported in Table 2.

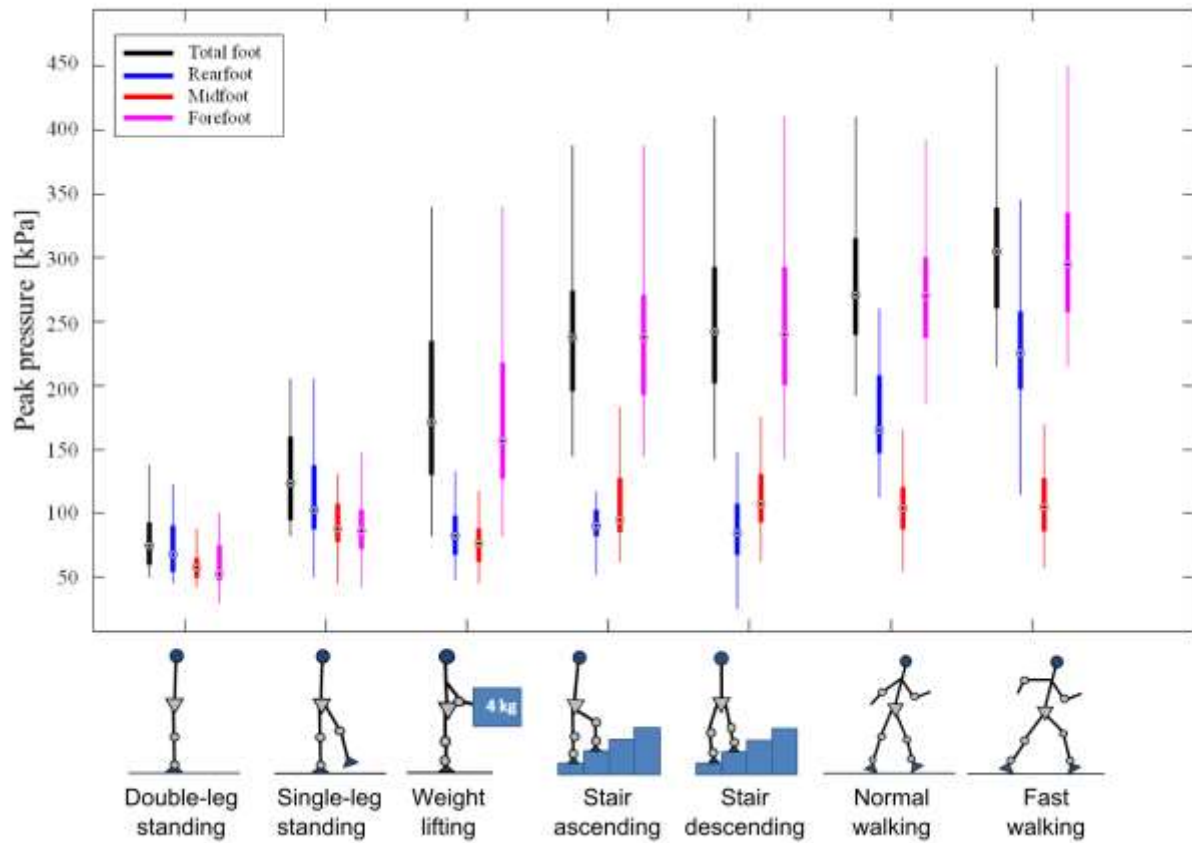


Table 1: From top to bottom, mean (\pm SD) of the maximum force (%BW), peak pressure (kPa) and time-normalized PTI (kPa) at rearfoot, midfoot and forefoot in the three insole groups for each of the seven motor tasks.

			Double-leg standing (12 s)	Single-leg standing (12 s)	Normal walking	Weight lifting (8s)	Fast walking	Stair ascending	Stair descending
Maximum Force [%BW]	Rearfoot	PSS	29.5 \pm 6.7	47.8 \pm 10.3	73.1 \pm 13.0 *	35.2 \pm 9.6	91.1 \pm 14.6 *	32.2 \pm 15.9	32.3 \pm 14.5
		OOT	28.7 \pm 7.3	48.9 \pm 10.6 *	72.3 \pm 11.5 *	37.4 \pm 9.2	90.7 \pm 12.0	33.0 \pm 14.0	31.1 \pm 11.4
		CUS	27.7 \pm 7.3	45.7 \pm 11.3	67.7 \pm 10.0	34.2 \pm 10.8	85.7 \pm 13.3	32.5 \pm 13.7	27.5 \pm 12.8
	Midfoot	PSS	8.6 \pm 3.6 *§	16.5 \pm 4.8 *§	16.7 \pm 5.1 *§	12.2 \pm 3.9 *§	18.6 \pm 5.5 *§	22.4 \pm 7.3 *§	23.9 \pm 7.8 *§
		OOT	11.8 \pm 3.7 *§	20.6 \pm 5.5 *§	22.0 \pm 6.7 *§	15.7 \pm 4.6 *§	21.2 \pm 6.1 *§	27.5 \pm 7.4 §	29.6 \pm 8.7 §
		CUS	14.0 \pm 3.4	23.6 \pm 6.4	24.7 \pm 5.9	18.3 \pm 4.5	24.0 \pm 6.1	28.0 \pm 6.0	32.2 \pm 7.8
	Forefoot	PSS	17.8 \pm 5.9	33.1 \pm 12.4	105.2 \pm 13.7	52.9 \pm 15.3	111.5 \pm 16.7	94.9 \pm 15.0	86.1 \pm 13.2
		OOT	16.5 \pm 5.2	28.9 \pm 10.9	107.5 \pm 16.7	49.7 \pm 18.3	116.6 \pm 18.6	95.7 \pm 16.2	87.1 \pm 13.1
		CUS	16.8 \pm 5.1	30.1 \pm 11.5	104.9 \pm 16.7	49.9 \pm 14.2	113.9 \pm 18.6	93.9 \pm 15.5	84.7 \pm 12.5
Peak pressure [kPa]	Rearfoot	PSS	84.4 \pm 25.4 *	128.0 \pm 40.0 *	195.2 \pm 37.2 *	96.1 \pm 26.9	252.4 \pm 41.4 *	95.8 \pm 40.9	95.9 \pm 32.7
		OOT	90.0 \pm 41.8 *	140.9 \pm 52.7 *	206.2 \pm 56.3 *	109.3 \pm 41.5 *	260.1 \pm 50.6 *	103.9 \pm 49.3	101.6 \pm 41.9
		CUS	78.6 \pm 42.2	122.0 \pm 56.4	182.5 \pm 59.8	96.3 \pm 53.0	227.8 \pm 50.5	105.3 \pm 57.2	93.2 \pm 44.2
	Midfoot	PSS	54.6 \pm 30.7 *	81.6 \pm 23.5 *	92.1 \pm 28.9 *	66.5 \pm 19.0 *	104.6 \pm 31.2	103.3 \pm 32.4	99.9 \pm 31.1
		OOT	55.4 \pm 21.2	84.5 \pm 22.1	102.2 \pm 43.3	69.9 \pm 20.6	101.8 \pm 34.3 *	111.8 \pm 43.7	111.4 \pm 34.0
		CUS	60.2 \pm 17.2	92.7 \pm 24.7	107.5 \pm 32.2	79.0 \pm 24.0	110.7 \pm 31.1	105.3 \pm 29.6	112.8 \pm 29.1
	Forefoot	PSS	67.1 \pm 26.1	101.8 \pm 31.3	304.5 \pm 54.2 *	178.0 \pm 72.3	330.4 \pm 67.7 *§	256.7 \pm 68.3	264.0 \pm 67.8
		OOT	67.6 \pm 24.5	101.6 \pm 41.7	332.7 \pm 75.5 *	188.3 \pm 65.5	371.7 \pm 81.2 *§	283.0 \pm 65.4 *	286.3 \pm 68.8 *
		CUS	61.3 \pm 21.9	97.6 \pm 47.8	275.9 \pm 55.3	176.3 \pm 64.8	304.0 \pm 58.8	242.8 \pm 66.2	246.8 \pm 63.7
Time-normalized PTI [kPa]	Rearfoot	PSS	77.1 \pm 22.1 *	111.4 \pm 32.4	81.0 \pm 13.7 *	54.2 \pm 13.5	83.2 \pm 17.3 *	52.6 \pm 33.5	40.5 \pm 17.8
		OOT	83.6 \pm 39.5 *	124.4 \pm 47.6 *	90.1 \pm 40.2 *	67.8 \pm 35.9 *	82.4 \pm 17.7 *	64.2 \pm 43.3	51.4 \pm 45.3
		CUS	72.1 \pm 39.4	110.1 \pm 50.2	84.9 \pm 49.1	61.3 \pm 44.3	74.1 \pm 14.7	60.6 \pm 50.9	42.7 \pm 42.6
	Midfoot	PSS	50.9 \pm 30.7 *	72.4 \pm 18.8 *	52.2 \pm 17.3 *	46.2 \pm 13.8 *	49.9 \pm 18.4 *	61.2 \pm 20.2	53.4 \pm 25.4 *
		OOT	51.1 \pm 20.2	75.7 \pm 18.5	58.4 \pm 22.2 *	49.2 \pm 14.7	51.5 \pm 16.8 *	68.7 \pm 24.7	61.9 \pm 23.0

	CUS	56.7 ± 15.8	82.5 ± 20.7	65.5 ± 19.3	55.3 ± 13.5	58.3 ± 16.7	66.8 ± 18.2	62.8 ± 21.1
Forefoot	PSS	59.5 ± 25.8 *	83.0 ± 25.9	119.1 ± 21.5 §	88.2 ± 27.1	121.5 ± 18.4	126.1 ± 32.0	160.2 ± 39.7
	OTS	57.4 ± 20.5	82.1 ± 36.5	130.0 ± 24.7 *§	90.7 ± 28.4	131.8 ± 22.8 *	136.8 ± 36.8 *	165.2 ± 33.4
	CUS	50.8 ± 15.3	79.1 ± 38.7	114.1 ± 20.8	84.3 ± 28.0	115.8 ± 17.7	118.0 ± 34.2	149.0 ± 37.7

* denotes statistically significant difference between CUS and another insole group ($p < 0.017$).

§ denotes statistically significance difference between PSS and OTS ($p < 0.017$).

Table 2. Outcome of the Tukey-Kramer post-hoc test for task-to-task comparisons in peak pressure at total foot in the CUS group. The corresponding peak pressure distributions are shown in Figure 3. ns is non-significant statistical difference ($p > 0.0024$).

	double-leg standing	single-leg standing	weight lifting	stair ascending	stair descending	normal walking	fast walking
double-leg standing		ns	ns	$p < 0.0024$	$p < 0.0024$	$p < 0.0024$	$p < 0.0024$
single-leg standing			ns	$p < 0.0024$	$p < 0.0024$	$p < 0.0024$	$p < 0.0024$
weight lifting				ns	ns	$p < 0.0024$	$p < 0.0024$
stair ascending					ns	ns	$p < 0.0024$
stair descending						ns	$p < 0.0024$
normal walking							ns
fast walking							