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Title :

Are custom-made foot orthoses of any interest on the treatment of foot pain for prolonged standing workers?

Author names and affiliations :

Tristan Tarrade^{a,b}, Fabrice Doucet^c, Nicolas Saint-Lô^b, Maxime Llari^a, Michel Behr^a

^a Aix-Marseille Univ, IFSTTAR, LBA UMR_T24, F-13016 Marseille, France

^b Podo 3D SAS, ScientiFeet research department, 78130 Les Mureaux, France

^c Doucet podiatry, 24750 Trelissac, France

Corresponding author:

Tristan Tarrade
Laboratoire de Biomécanique Appliquée (LBA)
UMRT24 IFSTTAR - Aix-Marseille Université
Boulevard Pierre Dramard, Faculté de Médecine secteur-Nord,
13916 Marseille cedex 20, France
Email. tristan.tarrade@ifsttar.fr
tel: (+33) 6 83 81 21 71

1. Background

Although employee safety has become an increasingly important priority for companies, safety shoes are generally seen as a mere means of physical protection of the foot rather than as a means of preventing musculoskeletal disorders (MSDs). And yet, foot MSDs can be easily detected through painful and debilitating signs, which, if left untreated, may result in a high number of sick leave absences. In the United States, ankle and foot pain accounted for nearly 10% of pain-related sick leave causes in 2015¹. Based on the analysis of a survey performed on 35,372 workers from 27 countries of the European Union in 2010, it was reported that the prevalence of work-related lower limb pain was around 16%^{2,3}. And while they directly affect the work of employees, their possible causes and triggering factors have rarely been studied^{4,5}.

Understanding the etiology of foot pain within a work environment is vital to developing effective solutions. Prolonged standing has already been established as one of the leading causes of lower limb MSDs^{3,6}. In Europe nearly 50% of employees from economic sectors including industry, education or construction are said to have been exposed to such MSDs risk in the course of their work in 2010^{2,7}. Risks associated to prolonged standing include venous insufficiency⁵⁻⁸, motor impairments⁷⁻⁹, discomfort⁷⁻¹¹ and increased fatigue^{7,8,10,11}.

Moreover, differences in safety footwear design can directly affect plantar pressure, comfort, fatigue levels and muscle activation^{7,12}. This is why the use of compression stockings, floor mats or insoles in conjunction with safety shoes have been suggested as solutions to prevent the development of MSDs related to prolonged standing^{7,8}. Among those solutions, the use of foot orthoses that are customized according to the patient appears as a valid solution^{13,14}, especially within the context of workers, as two recent studies show^{15,16}. These two last studies have compared the effect of heat-molded orthoses, with 2-mm elements placed under hyperpressure areas¹⁵, and 3D-printed versus prefabricated orthoses¹⁶ on the plantar pressures and comfort levels of standing workers. Both studies had small sample sizes (<20) and the effect of custom-made foot orthoses on the treatment of MSD-related pain and balance parameters were not studied. Indeed, as previously described^{11,17} prolonged standing position and the resulting fatigue has a great effect on postural stability while foot orthoses may be an effective means of improving static balance^{18,19}.

The goal of this study is to assess whether custom foot orthoses can be of any interest in the treatment of MSDs among prolonged standing workers. To do this, a particular manufacturing technology (ie 3D printed foot orthosis) which has not been compared to a control group of another technology (eg resin thermoformed

foot orthosis) was arbitrarily chosen. This study wasn't focused on the assessment of foot orthosis technology but only focused on the observation of possible difference between the "without" and "with" foot orthosis conditions without excluding a possible placebo effect.

2. Methods

2.1. Study management

The study was conducted among production line voluntary workers working in a prolonged standing position as operators in a production plant of the food industry in Perigueux, France. This is a monocentric, repeated measures study which was carried out in three stages (Fig. 1).

During the first stage, the purpose of the study was presented to employees. A foot-health and a medical questionnaire were distributed to all volunteers and an informed consent form was signed. Inclusion criteria were: spending more than 50% of working time in a standing position, suffering from foot pain (minimum score of 2 on an 11-point numeric rating scale questionnaire). In order to improve population homogeneity and consequently statistical power, exclusion criteria were defined as follows: overweighting (BMI>40), suffering from major traumatic sequelae, having neuropathic feet, displaying major morphopathological symptoms (leg length discrepancy>10mm) and wearing visually worn safety shoes.

The selected employees were then invited to the second stage, three weeks later, for a 15-minute session. An examination and a 3D plantar scan (Fig. 2a) were carried out by a qualified podiatrist. Static balance (stationary standing position) and static and dynamic (walking condition) plantar pressure measurements were made using a force plate and in-shoe pressure sensors inserted in safety shoes with neutral insoles (NI) (Ortholite (Amherst, MA), thickness: 3mm, density: 160 kg/m³, hardness: 40-45 shore A). Foot orthoses (FO) were then made by the podiatrist, 3D-printed and glued to the NI. The foot orthoses coupled with the neutral insoles (Fig. 2b), further called FO-NI in the rest of the paper, were then adjusted to the safety shoes before being distributed to each employee 2 weeks later. Two brands of safety shoes were used (Jallatte®, Ergos®). All participants were asked to keep their same pair of safety shoes all along the duration of the study.

After three weeks of wearing the FO-NI daily, workers were invited to another 15-minute session for the third stage. Plantar pressure (both static and dynamic) and balance measurements conducted in the second stage were repeated, but this time with the FO-NI inserted in the safety shoes. The foot health questionnaire was

distributed once again. Workers who could not attend the second and third stages and who did not fully fill out the questionnaires were excluded from the study. This study has been previously authorized by the company and was approved by the institutional ethics committee.

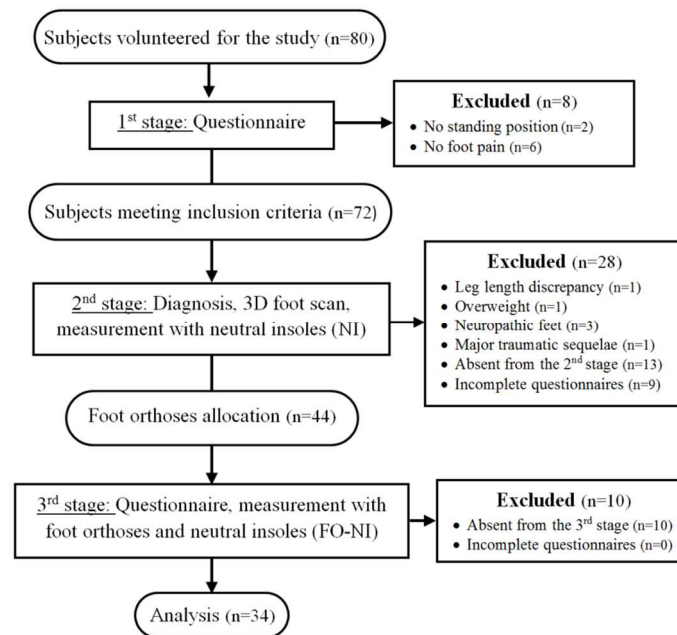


Figure 1: Flow chart of participants' recruitment and follow-up

2.2. Foot orthoses manufacturing process

Several weight bearing casting methods are available to make foot orthosis including non-weight-bearing, semi-weight-bearing or full-weight bearing conditions. The semi-weight bearing condition was chosen in this study as it was reported to provide the greatest peak pressure reduction compared to other insole designs²⁰. Foot geometry was acquired with a 3D footprint scanning device (PodoClic, Scientifeet, Paris, France). The device was pressed down on the unloaded foot by the same podiatrist (Fig. 2a). The 3D plantar shape was then scanned through the membrane and transferred to a dedicated application used to fit orthosis shape with footprint scan. FOs were then sent out to be printed in polyamide12 material with a 2-mm thickness by laser sintering and neutral insoles (NI) were glued to the surface of the FO (Fig. 2b). The overall fabrication cost of a pair of such customized foot orthosis is depending on the geometry and is lower than 50€.

2.3. Assessment of pain and comfort levels

In both first and third stages, workers were asked to assess pain and comfort levels in their questionnaires (before and after wearing FO-NI). The Foot Health Status Questionnaire (FHSQ) was selected for

its reliability²¹. The FHSQ comprises eight parts but only the first four parts were used within the framework of this study. The questionnaire assesses foot health during the past week in terms of Pain (type, intensity...), Foot Function (walking, working...), Footwear and General Foot Health. The questionnaire had previously been translated into French and reworked to include 12 questions by the French National Authority for Health²². The results were then processed by the FHSQ Data Analysis Software (version 1.03, P. Bennett) and converted into a score for each category between 0 and 100 (worst to best condition). In addition to the FHSQ questionnaire, foot pain, comfort levels and feelings of heavy legs were assessed on a 11-point numeric rating scale from 0 (zero intensity) to 10 (extreme intensity). The paired Student's t-test was used with a p-value set at 0.05.

2.4. Assessment of plantar pressures

In-shoe pressure sensors (Anatolog, Anatoscope, Montpellier, France) were used to measure peak pressure in eight foot areas (Fig. 2d). The system, consisting of 8 force sensing resistors (FSR) sensors of diameter 18 mm, transmits real-time pressure data with an acquisition frequency of 50 Hz to a dedicated application. The sensors were calibrated by the company before the measurements were carried out. Templates with sensor location were used to repeatedly position the sensors on the insoles (NI and FO-NI) according to the different shoe sizes. Each sensor was numbered and assigned to a measuring zone (Fig. 2d). The NI and FO-NI equipped with sensors were then inserted in the safety footwear to replace the original insoles. Pressure measurements were recorded in g/mm² for each sensor. The collected data were exported to CSV format and processed by Matlab R2016b. Three areas were defined from the analysis of the eight sensors: the forefoot area (hallux, 1st 3rd and 5th metatarsal head), the midfoot area (medial and lateral midfoot) and the rearfoot area (medial and lateral heel). Static measurements were carried out during the balancing test and mean pressure values for each sensor, each area and across the foot were calculated for 50 seconds. Dynamic measurements were also carried out during gait at free walking speed on a distance of 10m, four times in a row (40m in total). Five gait cycles per employee were extracted. The gait cycle, or stance phase, is defined from the heel-strike (when heel sensors start responding) to the toe-off phase (when hallux sensor stops responding). Average maximum peak pressure for each sensor, for each area and for the whole foot across the five gait cycles was recorded. The sum of average sensor response time values and the time-pressure integral were calculated as well. The paired Student's t-test was used with a p-value set at 0.05.

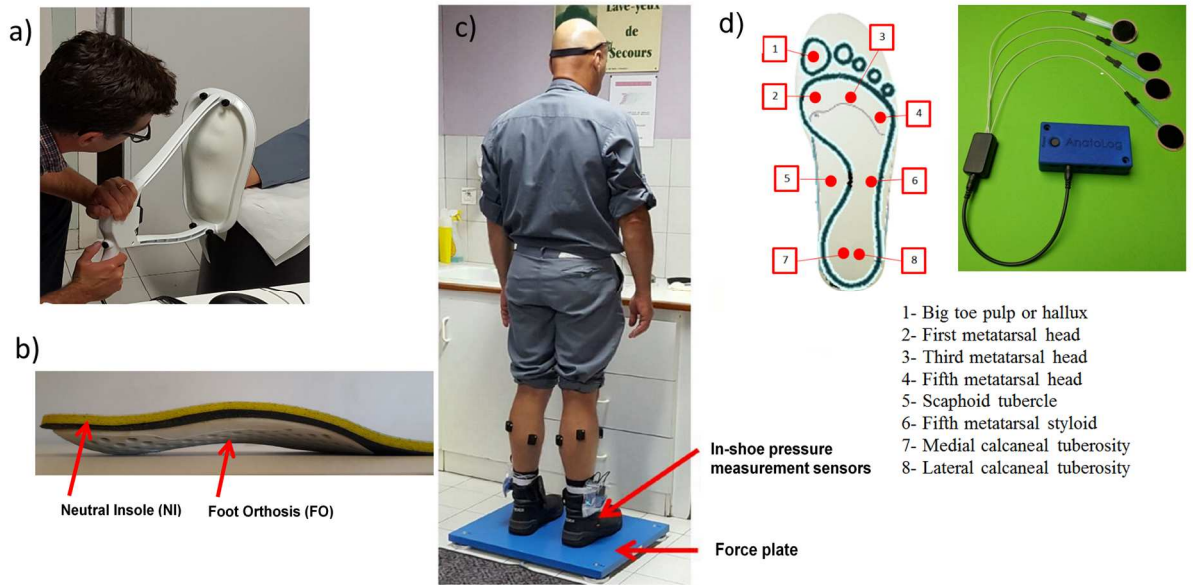


Figure 2 : a) 3D plantar scan with the PodoClic device, b) Foot Orthoses (FO) glued with neutral insole (NI) (FO-NI), c) Balance and static plantar pressure measurement, d) In-shoe pressure sensors and pressure measuring zone assignment

2.5. Assessment of balance parameters

The balance of the patients was tested with a Kistler 9260AA force plate (Kistler, Winterthur, Switzerland) at an acquisition frequency set to 100Hz. Patients were asked to maintain a static standing position in the center of the force plate, with relaxed arms along the body, loose jaw and eyes closed for a duration of 60 seconds (Fig. 2c). This instruction was given and repeated in the exact same way before every single measurement. Only one static measurement was performed because of the time allocated by the company. Although patients were asked to maintain a static standing position for 60s, only the last 51.2 seconds of data were extracted for further analysis as recommended²³. Data were processed by the MATLAB R2016b software (The MathWorks Inc., Natick, MA) and a 4th order Butterworth low-pass filter with a cut-off frequency of 5Hz was applied. The position of the center of pressure (COP) was determined and used to calculate COP path length, COP anteroposterior and medial-lateral velocity and amplitude of displacement, as well as the ellipse area that includes 95% of the COP positions. These parameters help understand the balancing strategies used by the employee before and after wearing FO-NI²⁴. An increase in those parameters would suggest a struggle in maintaining balance. The paired Student's t-test was used with a p-value set at 0.05.

3. Results

In accordance with the exclusion criteria, 34 employees, 27 men and 7 women (age: 43.8±10.9 years, BMI: 25.51±4 kg/m²), were selected for the study. Eight of the 34 participants wore prefabricated insoles in their safety shoes. The localization of pain and the identification of pathologies recorded via the questionnaire and the podiatric examination are detailed in Table 1. Two of the workers reported slight foot compression and were proposed a revised insole with a 2-mm-thick insole (NI) instead of 3-mm, making the assumption that this modification would not have significant effect (density: 130 kg/m³, hardness: 50-60 shore A).

Table 1: Overview of painful pathologies recorded by the podiatrist for the 34 patients at forefoot, midfoot and rearfoot

	Forefoot	Midfoot	Rearfoot
Number of patients	21	18	27
Pathologies	- Metatarsalgia - Morton's neuroma - Burning / overheating	- Plantar neuralgia - Plantar Fasciitis - Cramps - Burning / overheating	- Heel pain (tatalgia) - Plantar Fasciitis - Achilles tendonitis / calf cramps - Heel spur - Burning / overheating

Results from the FHSQ questionnaires and the numeric rating scale distributed before and after treatment are displayed in Table 2. Given the variability among workers of initial scores on the numeric scale (between 2 and 10), data were grouped together according to intensity: low intensity (from 0 to 3), moderate intensity (from 4 to 6) and severe intensity (from 7 to 10).

Table 2: Results of foot health questionnaires

		Intensity	Quantity of initial patients	Score before FO (SD)	Score after FO (SD)	General score before FO (SD)	General score after FO (SD)	P-value
Numerical rating scale	Pain	Low	9	2.0 (0.0)	1.1 (0.9)	5.3 (2.4)	2.0 (2.0)	< 0.05
		Moderate	16	5.4 (0.8)	1.7 (1.7)			
		Severe	9	8.2 (1.2)	3.3 (2.7)			
	Comfort	Low	11	2.5 (0.7)	0.9 (1.4)	5.9 (2.8)	1.4 (2.1)	< 0.05
		Moderate	6	5.2 (1.0)	1.7 (2.7)			
		Severe	17	8.3 (1.0)	1.7 (2.2)			
	Heavy legs	Low	11	1.7 (1.3)	0.8 (1.5)	5.3 (3.1)	2.1 (2.4)	< 0.05
		Moderate	9	4.8 (1.0)	2.3 (2.0)			
		Severe	14	8.4 (0.9)	3.1 (2.8)			
FHSQ	Foot pain	/	/	/	59.5 (28.5)	85.1 (18.7)	< 0.05	
	Foot function	/	/	/	69.9 (24.6)	92.8 (15.2)	< 0.05	
	Footwear	/	/	/	37.0 (24.5)	47.3 (27.6)	< 0.05	
	general foot health	/	/	/	38.5 (27.6)	59.0 (25.0)	< 0.05	

Because of wide disparities in the initial pressure values and balance parameters, due to differences in gait patterns, weight and morphopathological symptoms among workers, relative evolution of values were

calculated between the two stages using equation (1). E corresponds to the evolution in percentage, T1 to the result with NI and T2 to the results with FO-NI.

$$(1) E = ((T2_{\text{meanvalues}} - T1_{\text{meanvalues}}) / T1_{\text{meanvalues}} \times 100).$$

According to equation (1), positive evolution means that measured parameter increased with wearing FO-IN while negative evolution means that measured parameter decreased. However, statistical Student's paired T-tests were applied with the raw values. The results are reported in Table 3 and 4.

Figure 3 shows that maximum peak pressure was recorded in the rearfoot area. Differences were observed for peak pressure and evolution between left and right foot (Fig. 3 and Table 3). A two factor repeated measure analysis of variance test (ANOVA) revealed no significant interaction effect between foot laterality and support condition with the pressure parameters ($p\text{-value} < 0.05$) except for the 1st Metatarsal head sensor in dynamic. The cause of this difference is unclear and may result from slightly asymmetrical condition of footprint acquisition²⁵.

Table 3: Relative percentage difference of peak pressure per sensor and foot areas, of pressure activation time and of pressure-time integral after wearing FO for static and dynamic test configurations

	Static evolution (%)		Dynamic evolution (%)	
	Right foot	Left foot	Right foot	Left foot
hallux	-11.3	-24.8	-4.1	-4.6
1st MT^a head	-16.3*	-40.5*	5.1	-22.0*
3rd MT head	-12.6*	-7.1*	-0.8	-6.6*
5th MT head	-0.02	-8.1*	4.4	-13.8*
Medial midfoot	621.1*	611.9*	395.2*	396.9*
Lateral midfoot	16.6	51.7*	-2.5	23.1*
Medial heel	-33.7*	-19.8*	-15.9*	-13.8*
Lateral heel	-33.5*	-27.1*	-9.6	-27.5*
Forefoot	-9.6*	-17.8*	1.6	-12.1*
Midfoot	36.1*	85.3*	18.4*	53.5*
Rearfoot	-33.6*	-23.0*	-12.7*	-20.1*
Whole foot	-26.1*	-19*	-8.8*	-17.5*
Pressure activation time	/	/	15.0*	5.8*
Pressure-time integral	/	/	-1.9	-8.5*

^a MT = Metatarsal

* P-value < 0.05

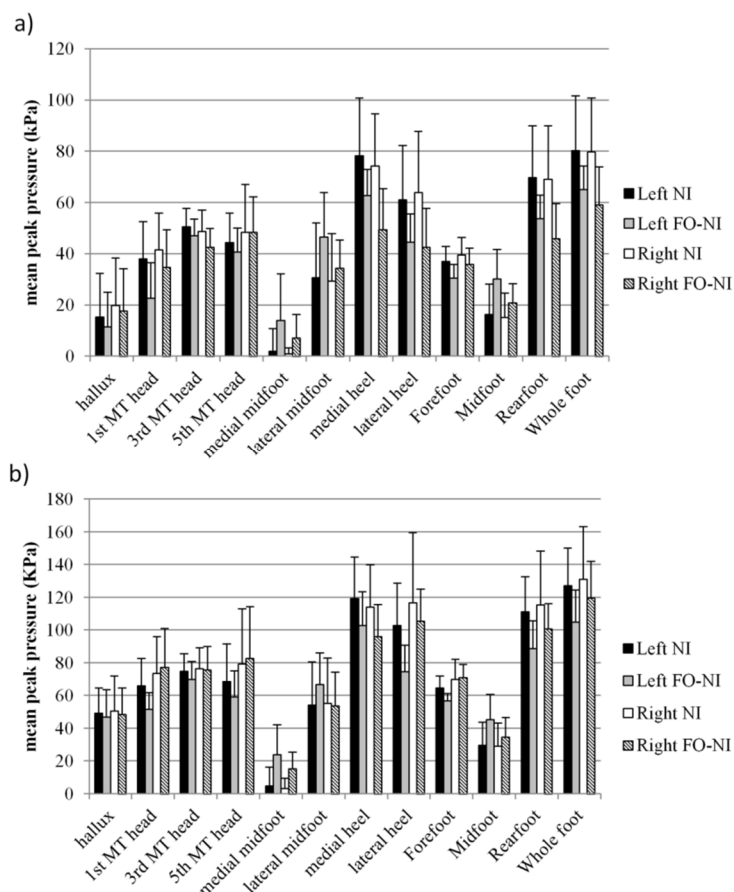


Figure 3 : Means and standard deviations of a) static and b) dynamic plantar peak pressure in initial condition (neutral insole) and with the foot orthosis for the right and left foot. MT=metatarsal, NI=neutral insole, FO-NI=foot orthosis and neutral insole

Table 4: Means, standard deviations (SD) and evolution of center of pressure parameters. NI=neutral insole, FO-NI=foot orthosis and neutral insole

Center of pressure parameters	NI (SD)	FO-NI (SD)	Evolution (%)	P-value
Total displacement of sway (mm) :	1682.9 (937.6)	1370.6 (380.6)	-18.6%*	< 0.05
Amplitude of anteroposterior displacement (mm) :	40.4 (26.5)	30.8 (17)	-23.7%*	< 0.05
Amplitude of medial-lateral displacement (mm) :	30.4 (15.9)	20.1 (9.7)	-34.0%*	< 0.05
Mean anteroposterior velocity (mm/s):	19.8 (15.3)	17.7 (5.7)	-10.7%	0.30
Mean medial-lateral velocity (mm/s):	21.9 (11.2)	16.7 (4.5)	-23.5%*	< 0.05
Sway area (95% of COP position) (mm²):	462.9 (659.8)	397.5 (755.2)	-14.1%	0.67

4. Discussion

Safety shoes are often mandatory and must meet stringent specifications to ensure the safety of workers against work-related risks (shocks, slipping). However, they appear to be rather poorly adapted to prolonged standing work conditions, one of the established causes of MSDs^{4,5}. As customized shoes, recommended by Anderson⁷ and tested by Caravaggi¹⁶, are not commercially available yet, one convenient alternative is the use of foot orthosis. In this paper, customized foot orthoses, designed from a 3D scan of the foot in semi-weight-bearing condition, were used and inserted into the safety shoes of 34 workers working in a standing position and suffering from foot pain. Assessment of pain, comfort levels, plantar pressures and balance before and after three weeks of treatment was carried out under identical experimental conditions (location, protocols, people and tools).

4.1. Questionnaires

A significant decrease in pain (-3.3/10), discomfort (-4.5/10) and feelings of heavy legs (-3.2/10) was recorded by a standard numeric scale after three weeks of wearing the FO-NI (p-value<0.05) (Table 2). The FHSQ questionnaire used in addition to the scale also showed significant improvements in the scores related to foot pain (+25.6), foot function (+22.9) and perception of general foot health (+20.5) (p-value<0.05). An improvement in terms of pain, discomfort and feelings of heavy legs score was noted respectively for 85%, 91% and 82% of participants. Despite differences in the designing process of foot orthoses, several studies corroborate these findings to some extent, with improvements in comfort levels ranging from 60-68%²⁶ to 72-90%²⁷.

4.2. Plantar pressures

Results from plantar pressure measurements reveal a significant difference in the peak pressure values under the whole foot. A statistically significant decrease of the maximum peak pressure values in static (-26.1% and -19%) and in dynamic conditions (-17.5% and -8.8%) (p-value<0.05) was observed (table 3). These figures are close to the 13.8% value reported by Tsung et al.²⁰ for FOs designed with footprints scanned under semi-weight-bearing conditions. This improvement could be explained by the increase contact surface between the insole and the foot. Indeed, an FO that is perfectly adjusted to the shape of the foot can support the weight of the entire body on a wider surface, which decreases the load per surface unit and redistributes peak pressure from the most stressed areas of the foot toward the sensor-free zones that were initially subject to lower stress. This

observation is confirmed by the statistically significant decrease of maximum peak pressure in the forefoot and rearfoot areas (p -value <0.05) and the statistically significant increase of maximum peak pressure in the midfoot area (p -value <0.05) in static conditions (table 3). The most significant variation of peak pressure was collected under the medial arch and it could be attributed to an absence of contact during first measurements with only neutral insole²⁸. The distribution of pressure toward the midfoot area has also been confirmed, to a lesser extent, by several studies^{14,18,26,27}. In dynamic and for a semi-weight-bearing foot scan, Tsung et al.²⁰ reported a +6% variation in the midfoot area and a -9.9% variation for the rearfoot area. In static conditions, the measurements recorded by Caravaggi et al.¹⁶ amount to +10% for the midfoot area against -6.8% and -8.6% for the rearfoot and forefoot areas respectively. The use of a limited number of pressure sensors (8) and the stiffness of the 2-mm thickness of PA12 material which is significantly higher than materials used in previous studies may explain these differences. Several studies have highlighted the influence of pressure distribution shifting toward the midfoot area in the relief of pain³⁰ and discomfort^{12,16,31}. The significant improvement in plantar pain, comfort, as well as the shift of peak pressure values from the forefoot and the rearfoot (painful) to midfoot confirm the key role that custom FOs play in taking the load off of painful areas exposed to excessive stress. However, the efficiency of the orthoses depends on the plantar scan procedure too. Indeed, FO that was designed from a low-weight-bearing foot demonstrated an arch higher than FO from a total-weight-bearing foot^{20,29}. This is why Tsung et al.²⁰ recommend that feet be scanned in semi-weight-bearing condition as a compromise solution so that the FO give enough support to the arches while avoiding the pain and discomfort that would occur were the FO too rigid^{29,31}. Nevertheless, the design and manufacturing processes of general foot orthoses present many variability factors connected to the techniques used to obtain foot shape²⁵ or the practitioner-specific manufacturing processes³².

4.3. Balance

Prolonged standing¹⁷, fatigue^{11,18} and pain³³ all affect postural activity. FO-NI tested during our study significantly reduce the amplitude (-34.0%) and the velocity (-23.5%) of the medial-lateral COP displacement, and the total displacement of sway (-18,6%) ($p<0.05$) (Table 4). These results, as well as the absence of any significant difference in terms of anteroposterior velocity, are consistent with those recorded in previous studies^{18,19}. However, the recorded decrease for the area of the confidence ellipse was not significant contrary to what was observed in other studies³⁴. The observed differences may be explained by the various factors that vary from one worker to another: age, height, pathologies, feet posture, daily physical activity, fatigue, as well as by

the industrial context²⁴. Moreover, because of the time constraint imposed by the company, only a single static measurement was performed for each static condition. The reduced postural sway in the medial-lateral direction suggests an improvement in postural stability in this given direction. As suggested by Ochsendorf et al. custom-made foot orthoses adjusted to the foot morphology could reduce fatigue-related body sway by either stabilizing the subtalar joint or actively supporting the medial arch¹⁸. Indeed, maintaining the foot in neutral position appears to limit tension requested to stabilize the subtalar joint and particularly reduce tensile stress within plantar fascia²⁸. It was also demonstrated that the medial-lateral shifts of the center of pressure is correlated with the recruitment of plantar intrinsic foot muscles³⁵. As midfoot and rearfoot pain are commonly linked to inflammation of the plantar fascia, it has been suggested that tensile stress in the fascia could be reduced with the support of the foot arch²⁸ and that could explain why a pressure in the midfoot area may not increase symptoms. These findings could be confirmed by a record of the foot intra-muscular electromyographic activity. It therefore appears that a customized arch support contributes to supporting the heel in its neutral position. Medial arch support¹² and the neutral position of the heel²⁷ are all the more essential as they play a key role in the perceived comfort of shoes. In addition, the influence of plantar stimulation on the improvement of the venous drainage of lower limbs was revealed³⁶. This observation could be further supported in our study by connection between the shape of the orthoses and the significant improvement in the feeling of heavy legs, a condition that is usually associated with venous insufficiency. A direct measurement of this parameter using photoplethysmography could validate this hypothesis.

This study has several limitations that may be listed. A low number of sensors were used and consequently some peak pressure might be underestimated. Moreover, the effect of FO was only studied in short-term period and long-term benefit is unknown.

5. Conclusion

According to our study, custom-made foot orthosis appears as an effective and simple solution to relieve foot pain in prolonged standing workers. As previously noted, it is not possible at this stage, and without further study with a control group and a larger sample, to conclude that 3D technology is of particular interest. The placebo effect, already identified in this type of protocol by Hawke et al.³⁷, is obviously not excluded. Our observation remain interesting: foot orthosis for prolonged standing workers provide subjective and objective benefits.

- Peak plantar pressure values are reduced and distributed under the foot from the heel area toward the midfoot area
- Foot pain, comfort and heavy legs have been significantly improved for the majority of volunteers
- Postural stability is significantly better in the medial-lateral direction.

However, additional studies should be carried out to analyze the biomechanical behavior of such 3D-printed foot orthoses compared with pre-fabricated, or other types of custom-made foot orthosis, to treat specific pathologies.

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7. Declaration of interest

Mr. Tarrade reports personal fees and non-financial support from Podo3D, during the conduct of the study; personal fees and non-financial support from Podo3D, outside the submitted work.

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