biomech CONSULTING

Relationship between weight, activity level, EVA insole changes and plantar pressures

Insoles are currently the most frequently prescribed treatment for several foot pathologies. Apart from supporting the foot, one of the duties of insoles is to produce a proper distribution of plantar pressures. Therefore, the aim of this study was to quantify the relationship between subject's weight, activity level, changes in shape and properties of the insole material and the plantar pressures. Wear trials were carried out using generic insoles made of dual-density EVA to analyse the factors that significantly influence the plantar pressure parameters as well as the insole thickness variations in different parts of the insole. After a short term (10 days) in a real use scenario, significant changes in the considered plantar pressure parameters were observed due to weight and use, in agreement with bench testing results for these materials. Consequently, weight, impulse and activity duration are variables that should be taken into account when deciding about the materials chosen for insole construction.
Keywords: word; EVA, bench testing, orthotic, DMA, SEM, insole simulator

1- INTRODUCTION

Insoles are currently the most frequently prescribed therapeutic devices for several foot pathologies. A prescription can have several goals such as relief of the foot or shock absorption. Besides the correct balance of foot moments , one of the duties of insoles is to produce a proper distribution of plantar pressures and soft cushioning . Materials for such purposes should have a relatively low hardness (30-75 °Shore A) paired with a good recovery and a low compression set and maintain their ability to distribute forces over an extended period of use.

The most commonly used materials are closed cell foams, which offer an additional hygienic benefit.

EVA (ethylene-vinyl acetate) foams are frequently used due to their light weight, flexibility, improved toughness, higher resilience, lower Young's modulus, etc. compared to other polymeric materials. Different EVAs are characterised by variable polymer blends of ethylene-vinyl acetate copolymers which yield specific material microstructures and mechanical behaviour.

Foam fatigue, a form of failure that occurs in a structure that has been subjected to a dynamic and fluctuating stress, is due to the compression and recovery processes of the cellular structure which produce a decline in the initial compressive collapse stress (elastic limit) that consequently results in the softening of the material.

This fact makes insole effectiveness change over time because of the change in it mechanical properties and use, and consequently in its functionality also. In addition, the insole performance is also influenced by its overall thickness.

One problem associated to orthotics as therapeutic devices is the prediction of their lifetime. However, not much published information is available on lifetime tests and in-shoe performance of EVA insoles (in real use) and in some cases there is a lack of information about the characteristics of the foam.

Therefore, the aim of this study is to quantify the relationship between subject's weight, activity levels, changes in shape and properties of the insoles and the plantar pressures.

This work is part of a greater study in which a wide range of insole materials have been analysed and intends to help in the establishment of a predictive technique to choose the proper EVA material features as a function of the patients' weight and level of activity as well as to predict their lifetime.

2- METHODS

2.1. Subjects

24 healthy recruits of INESCOP staff (12 males and 12 females) with an average age of 36,4 years σ= 7,4), weight of 75,8 kg (σ= 7,4) and height of 170,1 (σ= 8,8) participated in the study, four of them dropped out. According to their daily activity, the subjects were assigned to four different activity groups: From low activity (mainly seating, <750min), medium (750min>activity>1200min) to high activity (mainly standing/walking, >1200min) levels. Prior to testing, all subjects signed informed consent forms.

2.2. EVA orthotic design

Generic insoles that had been designed using the IcadPan ®3D software (INESCOP, Spain) based on data from a previous foot anthropometric study were milled from a dual-density EVA sheet (see Figure 1). Average insole size was 41±3. Before this, a bench testing of both materials was carried out to characterise their mechanical properties and performance. Table 1 includes references to the standards and experimental description carried out for materials characterisation.

2.3. Data collection procedures

All subjects wore the insoles for 10 consecutive working days, for at least 8h a day, wearing the same kind of socks and footwear (KELME-MICHELIN STAR-TREAD 360º). The subjects' activity was monitored using a RT3 (Stay healthy, USA) waist-mounted activity monitor.

Plantar pressures were measured on day 1 (trial start) and 10 (trial end), for shoe alone and shoe with orthotic, using the in-shoe measurement PEDAR System (Novel, Munich, Germany) operating at 50Hz. The subjects walked on a treadmill at 5km/h for 3min, data were collected during the last 60s and taking 50 map·s-1. Participants also filled in a questionnaire about different aspects relating to comfort, design, fit, etc, at both the start and end of the trial.

Furthermore, the insole thickness, at defined zones, was measured every two days just before putting on the test shoes and insoles and 5min after taking them off at the end of the working day.

2.4. Data analysis

Data post-processing and statistical analysis was performed with the PASW Statistics 18 software (IBM Corporation, New York).

Maximal cell pressure (MCP), maximal mask pressure (MMP) and impulse (IMP) were calculated from the pressure data. On the one hand, the NOVEL data were exported as a matrix with 5x5mm cells and MCP represents the average (per steps) of the maximal pressure at a single cell inside each of the analysed masks.

On the other hand, MMP is defined as the step averaged maximal pressure attained considering the whole mask. Finally, IMP measured in N·s/kg is the impulse for the whole mask divided by the subject's weight. All three parameters were calculated for each step and averaged among steps. In order to analyse the plantar pressure data, the foot sole was divided in 3 regions as follows (Figure 2): forefoot (FF), midfoot (MF) and rearfoot (HE).

Plantar pressure measurements were statistically analysed by the Analysis of the variance with repeated measurements method with the aim of analysing the relationship between the established plantar pressure variables (MCP, MMP and IMP) as a function of time, activity and subject's weight.

For each variable, the effect of the different factors and interactions was analysed. In the cases in which they are significant, the differences between several factors levels were then evaluated.

For this study, two different factor levels were established: 1) Intragroup as insole status (no insole, day 1 and day 10); 2) Intergroup as subject's weight and activity. The assumptions of normality and homogeneity of variances also contrast, although ANOVA's technique is robust to violations of these assumptions. The data analysis is performed according to compliance or not of the assumption of sphericity (which replaces independence of errors).

Furthermore, the variation of the insole thickness in each of the three previously established plantar foot regions was evaluated. The thickness variations, calculated as a percentage, were analysed as a function of the activity level, [impulse x activity] and subject's weight. Data analysis was carried out through Univariate Variance Analysis method.

3. RESULTS

3.1. Materials insole characterisation

Insoles are made of two EVA polymers differing in density and hardness. Table 2 includes the main results obtained from the bench testing of both EVA materials. The material used for heel part (EVA1, blue colour) has a density of 290 kg/m3, a hardness value of 65 Shore AO and 41% resilience, meaning it returned 41% or absorbed 59% of the applied energy in testing. The forepart was made of a material (EVA2, orange colour) with a lower density and hardness (200 kg/m3 and 45 Shore AO) but similar resilience values (41%).

The stress-strain properties of both materials were evaluated. Compression was performed until 70% strain in 5 consecutive cycles. Figure 3 shows the first stress-strain cycle corresponding to both materials. Stress-strain behaviour of foams can be divided into three regions. At low stresses, the behaviour is linear (linear zone) and it is controlled by cell edges and cell faces in closed-cell materials such as EVA.

This region finishes when the structure collapses and a new zone begins (plateau zone). For closed-cells foams of low density, the stress increases when the strain does because of an additional contribution of the compression of the gas inside. Finally, at higher strains, opposite cell walls touch each other, producing a sudden increase in stress; this is known as the densification region.

From stress-strain curves, Young's modulus (E) and the collapse stress (σ_c) were determined: EVA1 (E=5,4 MPa, σ_c=315 kPa) and EVA2 (E=4,5 MPa, σ_c=125 kPa). Because higher compression stress than the collapse stress values is exerted on the insole when walking, an increasing remaining deformation is expected in foam service. Higher collapse stress will produce lower remaining deformation during shoe service.

Additional testing included dynamic fatigue evaluations. To quantify fatigue characteristics of insole materials (EVA1 and EVA2), an insole simulator (fatigue tester device) was used (Table 1) which is able to replicate in vivo conditions, such as similar loading profiles and temperature.

Cycling loading with a compression load of 250 kPa over 25 000 cycles was established. After this test, the rearfoot insole material (EVA1) showed that 11% of the deformation remained with slight differences in hardness and resilience (2%). In contrast, the forepart insole material (EVA2) showed higher differences in its properties such as thickness (-20%), hardness (-6%) and resilience (+5%).

After the dynamic fatigue test, the change in Young's modulus of both insole materials was evaluated using a dynamic mechanical analyser (DMA). Figure 4 shows stress-strain curves corresponding to both materials before and after dynamic fatigue testing.

3.2. Factors which significantly influence the plantar pressure parameters.

The ANOVA results showed that all of the factors (status and weight) significantly ($p<0.05$) affected the measured plantar pressure parameters. Table 3 summarises the factors which significantly influence the plantar pressure variables depending on the insole region (forefoot, midfoot and heel).

According to the results, different single (status and weight), two-way (status*weight and status*activity) and three-way (status*activity*weight) interaction effects were found as significant ($p<0.05$) depending on the considered region of the insole (forefoot, midfoot or rearfoot).
3.3. Factors which significantly influence insole thickness variations.

According to ANOVA's results, a significant relationship between cumulative load (expressed as IMP*activity) and decrease in thickness (Δthickness in %) was found. This two-way interaction effect was only statistically significant ($p<0.05$) for the META1 mask. Therefore, the higher the cumulative load, the higher the remaining compression of the META1 area on the insole.

Furthermore, after fatigue testing, microscopic structural changes of the insole material in real use were evaluated. Cross-sections of the insole materials were analysed for changes in microstructure and accumulation of micro-damages using a scanning electron microscope JEOL JSM-840 (Jeol, Japan) available at the University of Alicante's facilities.

Prior to this, the samples were gold coated to obtain good contrast. Figure 5 shows SEM micrographs corresponding to both insole materials before and after the wear trials.

4. DISCUSSION

A prefabricated orthotic based on a previous foot anthropometric study made of a dual-density EVA was designed, milled and studied.

The overall hypothesis of this study is that both dynamic foot pressure and compressive stiffness of the insole materials will initially decrease, and that with repetitive wear, the pressure and stiffness will begin to increase and eventually reach a level of potentially damaging high pressures. The overall hypothesis has partially been established.

First of all, fatigue characteristics of both insole materials were quantified using an insole simulator device which is capable of replicating in vivo conditions, such as similar loading profiles and temperatures.

After this test, both materials showed remaining deformation as well as differences in hardness and resilience. After dynamic fatigue, there was a softening of the materials due to a decrease in Young's modulus and compressive modulus as well as its ability to dissipate energy (Figure 4), which were related to changes in the viscoelastic properties of the materials. Dynamic fatigue produced greater changes in mechanical properties for lower density materials (EVA2>EVA1).

Regarding in vivo testing, only ten-day use produced significant changes in plantar pressure distribution as well as insole thickness. On the one hand, compared to the shoe alone condition (status) prefabricated insoles under study resulted in reduced peak pressure in the three different areas considered: forefoot (FF), midfoot (MF) and rearfoot (HE). Furthermore, plantar pressure variables such as maximal cell pressure (MCP), maximal mask pressure (MMP) and the mean impulse (IMP) were significantly influenced. This fact can be related to the orthotic performance and effectiveness as well as the insole comfort, according to previous studies .

An ideal redistribution of pressure and soft cushioning over time is very important to treat or prevent several foot pathologies.

Moreover, plantar pressure variables were significantly influenced by the weight in the midfoot and heel areas. This fact may be correlated to relatively large stresses sustained by the calcaneo-cuboid joints and the posterior articulation of the subtalar joint in the midfoot and rearfoot regions.

Cumulative load (expressed as impulse x activity) during 10 days wearing also affected insole thickness only in the forefoot region (Meta1) producing also an increase in plantar pressure in this area. Frequent maximum pressure peaks were registered in the forefoot area due to several foot pathologies.

Therefore, they may produce high remaining deformation at Meta1 in soft materials paired with low recovery and high compression set (EVA2). Furthermore, scanning electron microscopy showed accumulation of micro-damages in cross-sections of the insoles in forepart materials after wear trials.

5. CONCLUSIONS

Even in a short-term real use scenario study (10 days), significant changes were observed in the plantar pressure parameters due to weight and activity (status). Cumulative load during 10 days wearing also affected insole thickness in the forefoot region (Meta1), in agreement with bench testing results for this material (EVA2).

Consequently weight, impulse and activity duration are variables that should be taken into account when deciding about the EVA materials chosen for insole design. In addition, further research is necessary in order to predict orthotic lifetime as a function of patient's individual needs.

The changes observed in the short-term tests suggest that care should be taken when interpreting insole effectiveness tests with new orthotics, since they might not represent the performance on a longer term basis.

Acknowledgement

The research was partially supported by the Spanish Ministry of Economy and Competitiveness (MINECO) through the project IPT-2012-1299-300000; and SSHOES project (NMP-2008-SME-2-R.229261) which has been co-funded by the European Commission within the Seventh Framework Programme.

6. REFERENCES

1- Kirby KA, 1989: *Rotational equilibrium across the subtalar joint axis*. Journal of the American Podiatric Medical Association,79(1):1-14.

2 - Simon K. Spooner, S. K.; Smith, D. K.; Kirby, K. A, 2010: *In-Shoe Pressure Measurement and Foot Orthosis*. Journal of the American Podiatric Medical Association, 100: 518-529.

3- Angel Camp Faulí, Cristina Llobell Andrés, Norberto Porta Rosas, Maria José Fernández, Enrique Montiel Parreño, César Orgilés Barceló, 2008. *Physical Evaluation of Insole Materials Used to Treat the Diabetic Foot*. Journal of the American Podiatric Medical Association, 98 (3): 229-238.

4- L. J. Gibson, M.F. Ahsby. *Cellular Solids: Structure and Properties, 2nd ed. Pergamon:* Oxford, 1988.
R. Verdejo, N. J. Mills, 2004. Heel-shoe interactions and the durability of EVA foam running-shoe midsoles. Journal of Biomechanics, 37, 1379-1386.

5- J. G. Foto, C. Ped, J. A. Birke, 1998. Evaluation of Multidensity Orthotic Materials Used in Footwear for Patients with Diabetes. Foot & Ankle International, 19 (12): 836-841.

6- Lawrence A. Lavery, Steven A. Vela, Hisham R. Ashry, Dan R Lanctot, Kyriacos A. Athanasiou, 1997. *Novel Methodology to Obtain Salient Biomechanical Characteristics of Insole Materials*. Journal of American Podiatric Medical Association, 87(6): 266-271.

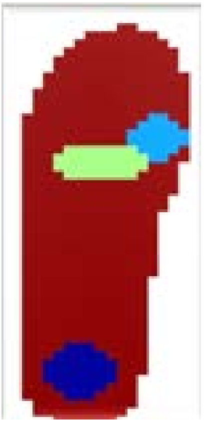
7- Jason Tak-Man Cheung, Ming Zang, 2005 *A 3-Dimensional Finite Element Model of the Human Foot and Ankle for Insole Design*. Arch Phys Med Rehabil. 86:353-358.

8- Martínez-Nova, A; Pascual Huerta, J; Sánchez-Rodríguez, R, 2008. *Cadence, Age, and Weight as Determinants of Forefoot Plantar Pressures Using the Biofoot In-shoe System.* Journal of the American Podiatric Medical Association, 98:302-310.

7. FIGURES

Bi-density EVA sheet

orthotic design used in this study



Plantar pressure masks: forefoot (FF), midfoot (MF) and heel (HE).

8. TABLES

Table 1. Standards used for material characterization tests.

Material property	Standard method
Apparent density (kg/m^3)	Standard ISO 845:1988
Hardness (Shore A)	Standard ISO 7619-1: 2011 The reading was taken 3 s after application of the load. Tests pieces: 12 mm thickness.
Resilience (%)	Standard UNE 53604:1990 The energy absorption capacity (expressed as % of the energy applied which is returned), tested using a modified Schob pendulum (model 645; Instruments J. Bot. S.A, Barcelona, Spain). Impact energy of 0,2 J was used. Test pieces: 12 mm thickness.
Stress-strain in compression test	All the mechanical properties were measured using a universal testing machine Instron model 5500R6025. Compression was performed till 70% of strain in 5 cycles, one just after the other following the standard EN ISO 3386-1
Compression fatigue test (%) (dynamic method)	Standard UNE 59536: 2007 The remaining deformation of the material after repetitive compressive loads (250 kPa) at 1 Hz over 25,000 cycles (Compression Fatigue Test Machine, model 5049, MUVER, Petrer, Spain). Measures were taken 30 min and 24 h after the end of the fatigue process. Test pieces: 29 mm diameter, 10 mm thickness.

Table 2. Physical properties of both EVA insole materials.

Material/property		Density (kg/m^3)	Thickness (mm)	Hardness (°Shore AO)	Resilience (%)
EVA 1 (blue)	Initial	290	12.9	65	41
	Fatigue	-	11.5	64	40
	Variation (%)	-	-11.0	-2	-2
EVA 2 (orange)	Initial	200	11.0	45	39
	Fatigue	-	8.8	43	41
	Variation (%)	-	-20.0	-6	+5

Table 4. Factors significantly influencing insole thickness variations in the established three regions of the insole (forefoot, midfoot y heel).

	Forefoot (meta 1)	Midfoot (meta 2-3-4)	Rearfoot
$\Delta_{thickness}$ (%)	Acumulative load	-	-