The Specification and Evaluation of Personalised Footwear for Additive Manufacturing

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ABSTRACT

Although additive manufacturing (AM) has potential in producing personalised items, such as footwear, it is unknown how to best capture and measure the foot in this context nor the short and medium term impact of such footwear on discomfort and injury risks. Therefore, research is currently being conducted to evaluate the short and medium term use of personalised footwear in terms of discomfort and injury risk; to identify measurement techniques for specifying and evaluating such footwear; and to determine the measurements required to specify personalised footwear suitable for additive manufacturing.

Participants had both feet scanned and 16 anthropometric measurements of the right foot taken. A single-blind paired samples experimental design was used and participants were paired according to: gender, age, body mass index and km ran per week. Thirty eight runners (19 pairs: 9 male pairing and 10 female pairing) were recruited. The two experimental conditions were: control and personalised. The personalised condition consisted of a pair of trainers fitted with personalised glove fit insoles that were designed and manufactured from the foot scans to match the exact plantar geometry of the individuals' foot. The control condition consisted of the same trainers, but fitted with a pair of insoles that were manufactured from the scans of the original insole shape, using the same material and thickness as the personalised condition.

Participants were allocated to one of the two experimental conditions and asked to wear the footwear for 3 months. Participants attended laboratory sessions at the start of the study (month 0), halfway (month 1.5) and at the end of the study (month 3) where the footwear was evaluated in terms of discomfort and injury risk. Discomfort was evaluated using a visual analogue scale. Injury risk was evaluated from plantar pressure distribution, rearfoot eversion, tibial internal rotation and peak vertical impact force of the right foot. The proposed paper will present the detailed methodology and approach of the study and discuss the early findings.

Keywords: Footwear, Additive Manufacturing, Anthropometry

INTRODUCTION

Additive manufacturing (AM), formerly known as rapid manufacturing, is potentially promising for producing personalised components, because of its geometric freedom and tool-less capability. In addition, AM can reduce unit costs, allowing production near the location they will be used, minimizing transportation and stock space (Hopkinson and Dickens, 2001).

The personalisation of footwear, in particular, can be advantageous for population groups, including older individuals, people with arthritis or diabetic foot problems. Personalised shoes can potentially provide a 'perfect fit' for the wearer. Studies indicated that 'fit' is the most important component of footwear not only because it is strongly correlated to comfort, but because it is speculated to be linked to injury and damage prevention (Cheng and Perng, 1999; Wunderlich and Cavanagh, 2001; Luximon et al., 2003). Too little or too much space in a shoe can be perceived as tight or loose respectively (Witana et al., 2004). Too tight a shoe will compress tissues leading to discomfort whereas too loose a shoe will lead to tissue friction because of the slippage between the foot and the shoe both causing blisters (Cheskin et al, 1987). In addition, poor shoe fit can cause undue pressure on the toes which can lead to deformities (Kouchi 1995; Kusumoto et al., 1996). In relation to specific population groups, a good fit can be even more important. For instance, recent reports indicate that the elderly population has wider feet than the shoes currently on the market, so they tend to develop forefoot pathologies (Chantelau and Gede, 2002; Menz and Morris, 2005). Also, individuals with diabetes have reduced pain sensation, so, unlike other population groups, they will not stop wearing footwear it is poorly fitted and this can start to damage the tissues (Chantelau and Gede, 2002).

The personalisation of footwear can also address personal preferences in terms of comfort. As comfort is influenced by an individual's foot characteristics, there is no comfortable shoe for everyone (Miller et al., 2000). Comfort is important because it is the main aspect that is considered when purchasing footwear (Cavanagh, 1980) and because it allows runners to maintain aerobic work for long periods of time (discomfort precedes pain).

In order to specify personalised footwear that is optimal to the individual, it is important to stress the importance of anthropometry. To provide a good fit, it has been speculated that at least 2 measurements in different dimensions in each region of the foot (forefoot, midfoot and rearfoot) are needed (Goonetilleke et al., 1997). The important measurements in determining individual preferences/needs, include instep girth, bottom width, heel height and toe box space (Goonetilleke et al., 1997; Cheng and Perng, 1999; Witana et al., 2004). Furthermore, foot shape plays an important role in the development of many types of injury (James et al., 1978; McKenzie et al., 1985; Cowan et al., 1993). Low arched (LA) individuals are likely to have more discomfort and greater rearfoot eversion because the lack of the arch and, consequently, the lack of shock absorbing capability leads to more foot and back injuries (Cheng and Perng, 1999; Williams III et al., 2001a). In addition, LA tend to prefer soft insoles in comparison to high arched (HA) runners that prefer harder ones (Mundermann et al., 2003). On the other hand, the HA foot is characterized by the longitudinal arch being more rigid, which makes it less efficient at absorbing impact shocks. They have more rearfoot inversion, resulting in higher lateral loadings and higher peak pressures (Cavanagh, 1980; McKenzie et al., 1985, Morag and Cavanagh, 1999; Williams III et al., 2001b). These are associated with a greater risk of injury, especially tibial shock, mechanical trauma and knee injuries (Cavanagh and Rodgers, 1987; Williams III et al., 2001a).

Although AM has much potential in the footwear field, it is not known how best to measure feet in this context nor even whether the short and medium term use of personalised footwear can affect discomfort and injury risk in comparison to the generic shoes currently available on the market. Hence, a 3 month study is being conducted at Loughborough University to investigate personalised footwear by providing participants with an AM glove fit insole. It is speculated that an insole which closely matches the foot of the individual will be more comfortable and reduce plantar pressure in comparison to a standard insert (Mundermann et al., 2003; Goske et al., 2006).

Therefore, the main objectives of this research are: (1) to evaluate the short and medium term use of the personalised footwear in terms of discomfort and injury risk; (2) to identify measurement techniques for specifying and evaluating such footwear; (3) and to determine the measurements required for specification for additive manufacturing.

METHODS

Recreational runners were recruited from gyms, running clubs, leisure centres and word by mouth in the Leicestershire area in the UK. Sampling criteria were: to run at least 5 $km.wk^{-1}$; have no reported musculoskeletal pain or injury for the last 12 months; 18-65 years old; and to have not used an orthosis for the last 12 months. A single-blind paired samples experimental design was utilized and participants were paired according to: gender, age, body mass index and km ran per week. The study was approved by Loughborough University's Ethical Committee. A total of 38 runners (19 pairs: 9 male pairings and 10 female pairings) were recruited. Participants were allocated to one of the two experimental conditions: control and personalised. Each experimental condition will be detailed in the next section. The footwear was evaluated in terms of discomfort and injury risk throughout a 3-month period. For that, participants were asked to attend to 4 laboratory sessions.

In laboratory session one, detailed anthropometric measurements were taken of the right foot following Hawes and Sovak (1994). The 16 measurements included girths, lengths, widths and heights.

Calculations enabled the classification of individuals according to the medial longitudinal arch:

- Arch ratio – height of the dorsum of the foot from the floor at 50% of the foot length divided by individual's truncated foot length (Williams and McClay, 2000);
- Arch index – calculated as the ratio of the navicular height to the foot length (Williams and McClay, 2000);
- Relative arch deformation (RAD) – calculated as:

$$RAD = \left(\frac{AHU - AH}{AHU}\right)\frac{10^4}{bodyweight}$$

where AHU is the measurement of the arch height taken in unloaded (i.e. 10% of weight bearing) position, AH is the arch height measurement taken in a full weight bearing (i.e. 90% of weight) position (Nigg et al., 1998).

Participants then had both feet scanned using a 4-camera 3 dimensional laser scanner (model: RealScan USB 200; 3D Digital Corporation, Newtown, CT, USA). Scans were taken with participants sitting on a chair, slightly resting their foot on the glass of the scanner (Figure 1).

Figure 1. Participant having the foot scanned.

EXPERIMENTAL CONDITIONS

After the first session, the insoles (control and personalised) were designed and manufactured, as described below.

The personalised condition consisted of a pair of New Balance trainers (model: NB-757 Neutral Cushion) fitted with personalised 'glove fit' insoles. These insoles were designed and manufactured from foot scans to match the exact plantar geometry of the participants' feet from the heel to the base of the metatarsal heads. The foot scan data taken during the first session were manipulated (i.e. data were 'cleaned' to remove the 'noise' and unwanted data, smoothed, thickened to 2 mm and converted into a STL file) using a Geomagic Studio 10 software (version: 10; Geomagic, Inc, Durham, USA). Parts were manufactured from DuraForm PA (polyamide), using selective laser sintering, an AM process technology. The process was similar to the one described elsewhere (Salles and Gyi, 2009). The 2 mm thick insole made them relatively rigid, providing heel and arch support, but not correction of lower limb abnormalities.

The control condition consisted of the same trainers, but fitted with a pair of insoles that were manufactured from the scans of the original trainer insoles, using the same material and thickness as the personalised condition. Thus, the control condition had identical shape as the trainers' original insole, but was manufactured using additive manufacturing to have same hardness and material as the personalised insole.

After parts were manufactured, a microporous polyurethane foam was used to cover both insoles. This was to provide some comfort to the individuals and to make sure the insoles would fit the inside of the trainers. Hence, the only difference between the two conditions was their geometry: one was generic (control) and the other was personalised (personalised).

LABORATORY SESSIONS

The laboratory sessions are detailed in Table 1. Sessions 3 and 4 took place approximately 6 weeks (1.5 months) and 12 weeks (3 months) after session 2 respectively. The shoes were given to participants in session 2. Individuals were asked to only wear the pair of footwear trainers for jogging/running and were encouraged to contact the investigator if they had any concerns.

Table 1. Laboratory session schedule for the participants.

Week – Lab session	Data collected
Week 1 – Lab session 1	Anthropometric measurements of the foot; foot scans
Week 4 – Lab session 2	Discomfort and injury risk
Week 10 – Lab session 3	Diary, discomfort and injury risk
Week 16 – Lab session 4	Diary, discomfort and injury risk

Sessions 2, 3 and 4 followed the same protocols for the collection of discomfort and injury risk data. Discomfort was evaluated using a 150 mm visual analogue scale. Injury risk was evaluated measuring plantar pressure distribution, rearfoot eversion, tibial internal rotation and peak vertical impact force of the right foot. At the end of session 4, the pair of trainers (with the original insole) used in the experiment were given to the participants.

DISCOMFORT ASSESSMENT

At the end of the laboratory sessions, participants were given a 150 mm Visual Analog Scale (VAS) to measure self-perceived discomfort. The VAS was similar to one used by Mundermann *et al.* (2002), with the left of the scale indicating 'the most comfortable condition imaginable' and the right 'not comfortable at all'. Six aspects of the foot were covered: heel, midfoot, forefoot, fit, arch and overall (whole foot).

INJURY RISK ASSESSMENT

Injury risk was assessed from the biomechanical data collected: plantar pressure distribution, rearfoot eversion, tibial internal rotation and peak vertical impact force. The literature suggests that high values are positively related to increased injuries in runners (Nigg et al., 1998; Hreljac et al., 2000; Mundermann et al., 2004; Yung-Hui and Wei-Hsien, 2005).

To ensure that individuals ran at a speed of 2.78 m/s (± 5%), electronic timing gates (model: SmartSpeed; Fusion Sport, Brisbane, Australia) were positioned in the middle of a 10-meter runway. Therefore, before starting the data collection, participants had 5 practice trials to run for 10 meters in order to familiarize themselves with the required speed. After that, an F-Scan Mobile (Tekscan Inc, South Boston, MA, USA) in-shoe plantar pressure distribution sensor (N/cm^2) was placed inside the shoe and recorded at 250Hz. Participants then ran 5 times under the same experimental condition for 10 meters whilst plantar pressure distribution was recorded. For the purpose of data analysis, the foot was divided in three regions: heel, midfoot and forefoot. Plantar pressure was captured for each region using a F-Scan Mobile Research software (version, 5.72; Tekscan Inc, USA). The mean of the peak pressure values were taken for each region of the foot during ground contact.

After 5 valid trials (i.e. speed was within the range accepted), the plantar sensor was removed from the shoe and 16 reflective markers (14 mm diameter) for tracking 3D movement were placed according to the Plug-In-Gait standard lower body modeling. Participants were then asked once again to run 5 times at the same speed range (2.78 m/s ± 5%) while kinematic data were collected with a 12 camera Vicon MX system (400Hz; Oxford Metrics, Oxford, UK). Ground reaction force was recorded at 800 Hz and the force plate (type: 9281; Kistler Instrumente AG, Winterhur, Switzerland) was synchronized with the kinematic data. For data analysis, tibial internal rotation, rearfoot eversion and vertical impact peak of the ground reaction force were captured for each participant under each experimental condition. Since the rearfoot was considered fixed on the ground for the majority of the stance, tibial internal rotation was defined as rearfoot adduction/abduction (i.e. transverse plane motion of the ankle joint), whilst rearfoot eversion was defined as the frontal plane motion of the ankle joint. Impact peak was defined as the first peak in the vertical ground reaction force data. The forces were normalized as times body weight (bw) and the ankle joint angles were normalized in relation to the data taken with the individuals wearing the trainers fitted with its original insole. Ground reaction force values were also used to determine the moments of heel strike and toe-off in stance phase.

ACTIVITY DIARY

At the end of laboratory sessions 2 and 3, participants were provided with a pedometer (model: NL-800; New-Lifestyles Inc, Lee's Summit, USA) and an activity diary. They were instructed to wear the trainers and the pedometer every time they went jogging/running for a 3-month period as well as complete the diary after each training session. The activity diary captured information such as: how long the running shoes were worn, pedometer reading of steps taken, any discomfort felt and any additional comments. Discomfort was once again measured using a 150 mm VAS. The diary was returned to the researcher in laboratory sessions 3 and 4.

DATA ANALYSIS

The paired samples Student's *t*-test was used to detect significant differences between the two experimental groups for the variables (discomfort ratings, plantar pressure distribution, rearfoot eversion, tibial internal rotation and vertical impact peak) in months 0, 1.5 and 3. The level of significance was accepted as • • 0.05. Statistical Package for the Social Sciences (SPSS) software for Windows (Release 15.0, SPSS©, Inc., 2006) was used for all analyses.

The process of manipulating and manufacturing the insoles from the scans was evaluated according to the following: compatibility of the data taken from the foot scans (i.e. if the files worked in the Geomagic Studio 10 software), the software capability to manipulate the files, compatibility of the final data with the AM machines and durability of the material (DuraForm® PA).

RESULTS

The data collection started in June 2009. Thirty eight runners (19 pairings) have been recruited to take part in this research. To date, 4 pairings (8 participants) have completed the study. Six participants (2 from the control group and 4 from the personalised group) have discontinued the study. The paper will report on the data in relation to the 4 pairs of participants (Table 2).

Table 2. Descriptive (mean ± SD) statistics for the participants.

Group (n=8)	Age (yrs)	Height (cm)	Mass (kg)	Activity (km/wk)	Gender
Control (n=4)	39.25 ± 12.6	1.68 ± 0.07	61.5 ± 7.3	12.5 ± 8.7	2M and 2F
Personalised (n=4)	37.5 ± 11.7	1.66 ± 0.04	60.85 ± 3.95	11.25 ± 5.2	2M and 2F

The discomfort ratings taken in the laboratory sessions were generally low for both experimental conditions (Figure 2). The student's *t*-test indicated no significant differences between the two conditions throughout the 3-month period. However, participants reported less discomfort in the personalised condition, particularly in months 1.5 and 3.

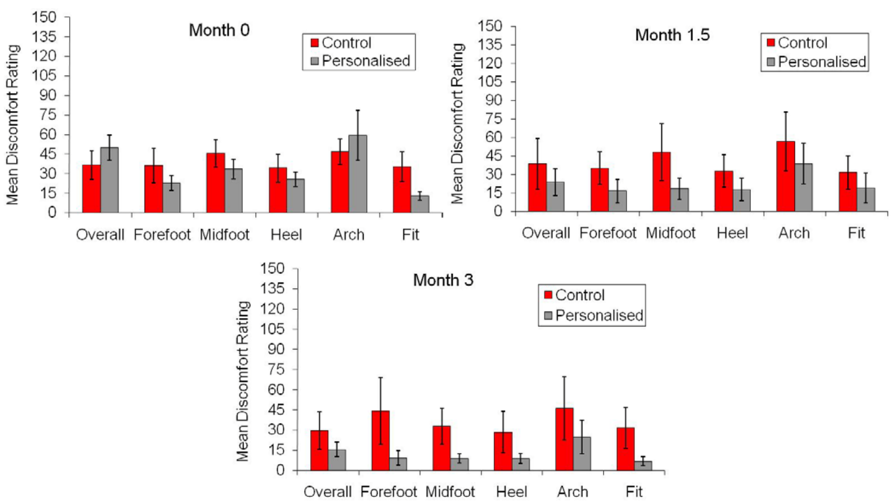

Figure 2. Mean discomfort ratings and standard error for the control and personalised conditions in months: 0, 1.5 and 3.

The mean values for rearfoot pronation and tibial internal rotation showed an increase in both conditions for the 3-month period, whereas vertical impact peak showed a reduction in the same period. On one hand, the pronation and tibial rotation values indicated an increase, while the vertical impact peak suggests a decrease in the risk of injury for the participants in the two groups. However, no significant differences were found between the control and personalised conditions for these injury risk variables over the 3 month period.

In addition, no significant differences were found between the two conditions for mean peak plantar pressure distribution (Table 3).

Table 3. Comparisons of mean peak pressure (unit: KPa) between the two conditions in months 0, 1.5 and 3. Data are presented as mean (SE).

Region	Condition	Month 0	Month 1.5	Month 3
Heel	Control	209.3 ± 69.2	219 ± 50.4	224.3 ± 71.4
	Personalised	211.6 ± 36.8	247.3 ± 12.8	208.4 ± 19.5
Midfoot	Control	99.9 ± 16.9	93 ± 14.7	103.3 ± 25.7
	Personalised	107.3 ± 20.6	103.9 ± 11.4	79.8 ± 6.4
Forefoot	Control	208.3 ± 52.5	190.7 ± 34.6	236.5 ± 67.7
	Personalised	245.5 ± 16.9	222.6 ± 17	167.9 ± 18.2

The activity diary supported the discomfort ratings taken during the laboratory sessions. The participants were instructed to report any discomfort (in any region of the body), during their running sessions. During the first 1.5 months of usage of the shoes, the participants in the control and personalised conditions experienced some discomfort in, on average, 63% (ranging from 40-75%) and 51% (30-85%) of their training sessions respectively. However, the analysis of the ratings indicated that this discomfort had a low mean rating. In the last 1.5 months of the study, on average, the runners in the control condition reported some discomfort in 38% (0-58%) of their training sessions, whereas the participants in the personalised group in 20% (0-80%). Both groups attributed their discomfort, in the majority of cases, to the insoles. Also, the arch region was the most cited area of discomfort by the two groups.

DISCUSSION

This study is currently being conducted and completion is expected in summer 2010. The data presented of four pairs of participants must therefore be interpreted carefully and in this context.

These preliminary results did not show any significant differences between the two experimental conditions for discomfort, but a trend can be noted. After a 1.5 month period, the personalised insoles had lower discomfort ratings for all the regions of the foot assessed. It is likely that the individuals need a period of accommodation with any footwear. The height and stiffness of the arch support, was found to be too intrusive in the beginning, but after 1.5 months they became used to it and their perception changed. The data from the activity diary supports this, especially with regards to the arch ratings. On the other hand, Mundermann *et al.* (2003) reports that custom made insoles are significantly more comfortable than a control flat insert for a period of 3 weeks only.

Yung-Hui and Wei-Hsien (2005) indicated that custom fabricated insoles can reduce plantar pressure, attenuate the impact force and are more comfortable than a shoe without such insoles. However, the injury risks variables did not show any significant differences or any patterns between the two conditions over the three month period. This is likely to be attributed to the small sample size.

The anthropometric measurements and scan data were used in the design of the personalised insoles. Two foot length measurements taken from the most posterior projecting point on the heel to the 1st and 5th metatarsal phalangeal joints indicated the length of the insoles. The navicular height was used to determine their height. As the discomfort ratings were low and the data were compatible with the software and hardware utilized, the process of the design and manufacture of the insoles was successful. The data taken from the scanner were compatible with Geomagic Studio. This software provided the appropriate tools to reduce the noise, delete unwanted data, fix the jagged edges on the boundary, smooth and thicken the parts in 2 mm. The final data file proved compatible with the AM machines. The material (polyamide) showed very good durability throughout the study. No signs of breaking were noted in the qualitative inspections during the laboratory sessions.

However, further analysis need to be carried out regarding possible correlations between the anthropometric data and the discomfort and injury risk variables. These will help with the identification of foot shapes that are more likely to develop discomfort and injuries.

In summary, the preliminary data set of four pairs showed no significant differences between the two conditions for the discomfort and injury risk variables for the 3 month period. The design and manufacture of the insoles were successful. Anthropometric measurements helped with the design, delimitating its length and height. The scan data were compatible with the software and AM machines and the material (polyamide) showed good durability.

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