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The specification and evaluation of personalised footwear for additive manufacturing

by

André Siqueira Salles

Doctoral Thesis

Submitted in partial fulfilment of the requirements
for the award of Doctor of Philosophy of Loughborough University

December 2011

Loughborough University

CERTIFICATE OF ORIGINALITY

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Abstract

The personalisation of footwear offers advantages not only for runners, but to anyone who wishes to become more active. Additive manufacturing (AM) technology has the potential for making footwear personalisation economically feasible by allowing direct manufacture from CAD models and its tool-less capability. This thesis aims to develop and explore the process of footwear personalisation using AM and evaluates such footwear in terms of discomfort and biomechanics.

To start to explore this process a repeated measures pilot study was conducted. Six recreational runners had anthropometric measurements of the foot taken and the plantar surface of both feet scanned. From the scans and measurements, personalised 'glove fit' insoles were designed and manufactured using AM. Participants were then fitted with footwear under two experimental conditions (control and personalised), which were compared in terms of discomfort, performance and biomechanics. The findings of this pilot confirmed the feasibility of the personalisation process.

A longitudinal study was then conducted to evaluate the short and medium term use of personalised footwear in terms of discomfort and biomechanics. A matched pairs study design was utilised and 38 recreational runners (19 pairs) were recruited. Control (generic shape) and personalised geometry insoles were designed and manufactured using AM. The participants wore the footwear each time they went running for a 3-month period. They also completed an Activity Diary after each training session and attended 4 laboratory sessions during this period. The results showed significantly lower discomfort ratings in the heel area and for overall fit with the personalised insoles. However, discomfort was reported under the arch region for both conditions (supported by the Activity Diary), indicating that the foot scanning position and material may need modifying. With regard to the biomechanics, the personalised insoles also led to significantly lower maximum ankle eversion and lower peak mean pressure under the heel, which are potentially positive effects in terms of reducing injury risk. A case study is then reported which explored foot capture using a dynamic scanner for the design and manufacture of insoles using AM. Through the development of four insoles, it was found that the selection and manipulation of the scan data from the series of frames generated during ground contact were the most demanding elements of the process. Finally, recommendations and guidance are given for the footwear personalisation process (foot scan position, anthropometry, insole design and AM), together with its potential benefits and limitations.

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Dedication

To my parents, Antônio Lafayette Salles and Deise Fernanda Siqueira who always offered the best and encouraged me in every stage of my life. Their never-ending support is my main source of inspiration and energy.

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Publications

GYI, D.E., SALLES, A., and PORTER, J.M., 2009. Elite to high street footwear: the role of anthropometric data. In: LOTUS, T., REITENBACH, M., and MOLENBROEK, J., eds. *Proceedings of the 9th International Congress of Physiological Anthropology*. The Netherlands: Faculty of Industrial Design Engineering, ISBN: 978-90-78809-80-7, pp. 53-56.

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Glossary of terms and abbreviations

3-D	:	three-dimensional
AHI	:	arch height index
AI	:	arch index
AM	:	additive manufacturing
AR	:	arch ratio
BMI	:	body mass index
CAD	:	computer aided design
CNC	:	computer numerical controlled
Duraform® PA	:	Nylon 12 material
E2HS	:	Elite to High Street research project
EVA	:	ethylene vinyl acetate
FDM	:	fused deposition modeling
FP	:	force platform
FS	:	foot strike
GRF	:	ground reaction force
ICC	:	intraclass correlation coefficient
LS	:	laser sintering
MLA	:	medial longitudinal arch
MPJ	:	metatarsophalangeal joint
MSP	:	midstance phase
Nylon 12	:	polyamide based material (Shore D 73)
PiG	:	plug-in gait
RAD	:	relative arch deformation
Rearfoot eversion/inversion	:	movement of the ankle joint in the frontal plane
RP	:	rapid prototyping
STL	:	de facto standard RP / AM file format
TIR	:	tibial internal rotation
VAS	:	visual analogue scale

Chapter 1: Introduction

1.1. *Footwear manufacturing and personalisation*

Before the industrial revolution, products were handmade to order by a skilled artisan to meet the demands of a local community. If someone wanted a pair of shoes, the tailor would take measurements, ask a few questions and build a single pair for that person only, by hand. The positive side was that every item was bespoke and unique. However, they were expensive so most people could not afford them. Without modern machinery and factories, production relied solely on human hands assisted by tools. After the industrial revolution, goods became mass produced, allowing a significant decrease in costs. Every item was identical and the options were reduced. In the case of footwear, although a shoe would not fit someone perfectly, it was ok because the product was cheap, so customers could afford many pairs. Over time, bespoke products based on individual requirements were replaced by generic, cheaper alternatives. This initial mass production doctrine gradually evolved to a globalised world and nowadays industry can deliver customised products made in China. In summary, technology has enabled the development of manufacture from craft production to current mass customisation and ultimately sustainable production, as shown in Table 1.1.

Table 1.1. Evolution of production paradigms (from Boer *et al.,* 2004).

Paradigm	Craft production	Mass production	Flexible production	Mass customisation and personalisation	Sustainable production
Paradigm started	~1850	1913	~1980	2000	2020?
Society needs	Customised products	Low cost products	Variety of products	Customised products	Clean products
Market	Very small volume per product	Demand > supply steady demand	Supply > demand smaller volume per product	Globalisation	Environment
Business model	Pull *sell-design-make-assemble*	Push *design-make-assemble-sell*	Push-Pull *design-make-sell-assemble*	Fluctuating demand Pull *design-sell-make-assemble*	Pull *design for environment-sell-make-assemble*
Technology enabler	Electricity	Interchangeable parts	Computers	Information technology	Nano/Bio/Material technology
Process enabler	Machine tools	Moving assembly line and DML	FMS robots	RMS	Increasing manufacturing

At the end of the 20th century, acknowledging the change in manufacturing ideals, the Federal Reserve Bank of Dallas (1998) released an annual report evidencing that the United States of America was moving towards mass customisation, transforming consumer behaviour and the products available. They stated:

"The rich have always enjoyed the luxury of custom made products. Now, though, personalized goods and services are increasingly within the budgets of middle-class consumers. Computers, the Internet, DNA research and other technologies are forging a whole new paradigm that makes possible the delivery of custom-designed products to the masses — at ever lower prices. The descriptive phrase for the phenomenon is mass customization. 'Once you know exactly what you want, you'll be able to get it just that way,' says Bill Gates, founder of software giant Microsoft." (Federal Reserve Bank of Dallas, 1998).

The Federal Reserve Bank of Dallas (1998) also reported a significant increase in product choices over more than 20 years. For example, the number of running shoe styles rose from only 5 in the early 70s, to 285 in the late 90s, and it is expected that this has increased further. Figure 1.1, shows an example of the running shoes currently available on the market according to their cost and the technology.

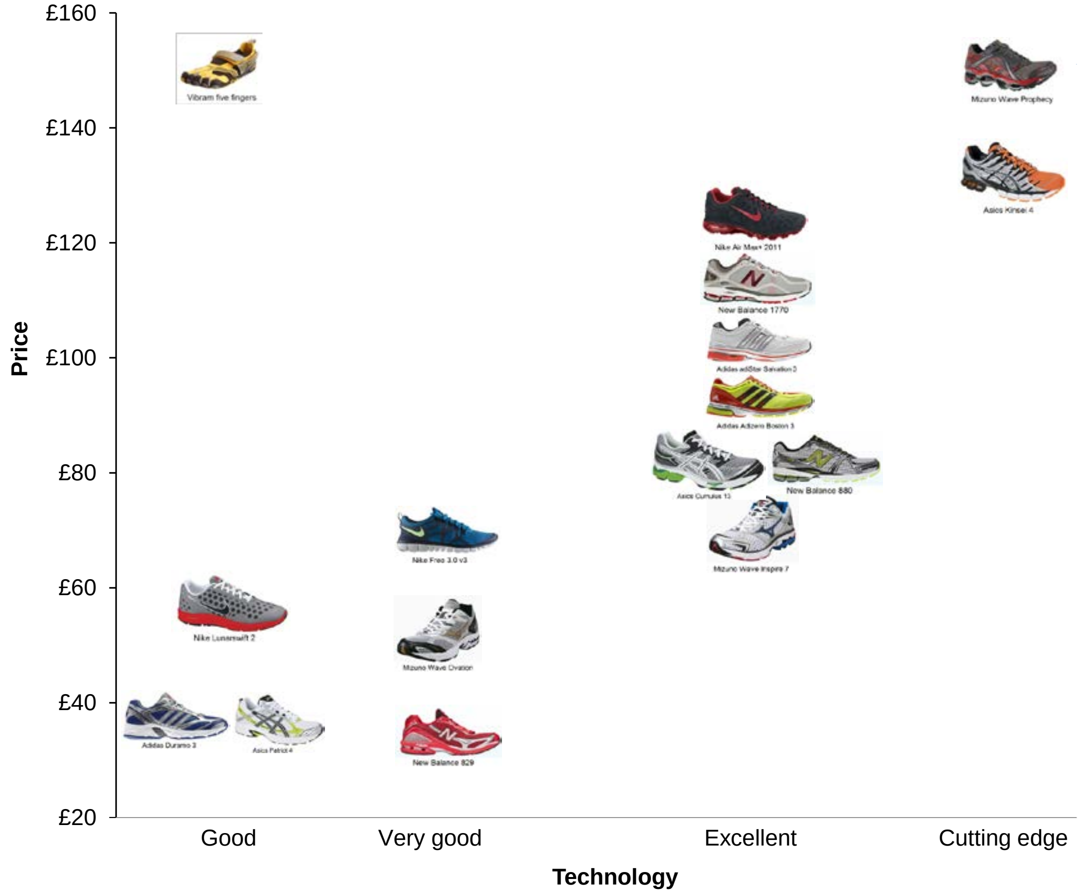


Figure 1.1. Diagram showing examples of running shoes currently on the market.

At the beginning of the 20th century, mass produced running shoes were purely made to accomplish a task (protect the foot) at an affordable cost. At the end of the century, trainers started to incorporate research and technology to their concept and, in the 00s, they gradually enabled the production of individual products (personalisation) provided by high innovation and flexibility, although tailor-made shoes were already available for top athletes (IMD, 2006). To exemplify this change, Table 1.2 shows the development of Adidas running shoes since the 1960s.

Table 1.2. Development of the Adidas running shoes (adapted from Adidas, 2009).

Decade	Focus of the market	Example	Shoe's innovative feature(s)
1960s	Reinforcement of various regions of the foot for more durability and wear.	 Rome	Extra padding to protect the ankle, heel and Achilles tendon.
1970s	Further development in the durability and wear properties.	 Country	Made of soft leather, had a wrap-around and double thick support in the heel and Achilles tendon.

Decade	Focus of the market	Example	Shoe’s innovative feature(s)
1980s	The beginning of footwear customisation capability.	 LA Trainer	Adjustable cushioning by allowing a variation in density using replaceable elements.
1980s	Also the 1980s was the decade when the footwear started to be developed based on biomechanical research.	 ZX 500	Guided by research, this shoe offered cushion at the heel, support during midstance and guidance to the foot during push-off.
1980s	Flexibility and comfort.	 ZX 8000	Better adaptation of the shoe to the ground by offering independent motion of the heel and forefoot.
1990s	Increase in types to suit different running styles and foot types.	 Equipment	The ‘Equipment’ line offered shoes with support, cushion or guidance for road racing,
1990s	Barefoot running starts to attract the interest of runners.	 Feet You Wear	The ‘Feet You Wear’ line offered products designed to “mimic the inherent stability, efficiency and rapid reaction of the bare foot” (Adidas, 2009).
2000s	Impact forces during running are still considered and shoes are designed to reduce them and provide support.	 adiStar	Reduction of impact forces, enhancement and support of natural movement.
2000s	Footwear customisation. Market becomes even more flexible.	 adidas_1	Sensors placed in the shoe, that made it ‘understand’ and adapt to the individual’s cushioning requirements.
2000s	Further advances on customisation.	 mi Climacool Ride	Mi adidas service launched in the beginning of the 2000s offers personalisation, but mainly aesthetics.
2010s	Technologies adapt to the individual requirements.	 adiStar Salvation 3	Technologies like Formotion^{TM} adapts the shoe to the ground and adiPrene® helps propulsion and efficiency.

Decade	Focus of the market	Example	Shoe's innovative feature(s)
2010s	Improvement of performance.	 Bounce:S²	Car inspired suspension system transfers vertical impact into forward propulsion.

According to Boer *et al.* (2004), there are levels of shoe personalisation (in this case, social shoes), which can be summarised as:

1. design customisation – the first level of personalisation, allows the customers to select aspects related to colours and materials or to small details like name printing, for example the mi adidas system (www.miadidas.com);
2. size and fit customisation – the second level of personalisation, offers a shoe built on the specific dimensions (e.g. width) and feet of the customer, in addition to the parameters offered at the previous level;
3. best fit approach – it permits customisation by identifying the 'last' style combination that is the best approximation of the customer's feet dimensions and requirements;
4. custom made approach – this more complete level of personalisation, allows the shoe to be manufactured meeting both dimensional and functional requirements.

Today, although some customisation of footwear is economically feasible (e.g. colour, fit options) and already exists, it still requires additional costs in comparison to the mass produced options. Two of the well established personalisation systems for trainers are: NikeID (www.nikeid.com) and the mi adidas system. Whilst the trainers sold through these systems are more expensive, consumers are willing to pay a premium of 10-30% on the current mass produced formal and casual footwear, determined by the level of customisation available, which is dependent on the individual's perception (EuroShoe Consortium, 2002).

Additive manufacturing (AM) is potentially revolutionary in developing personalised footwear, allowing manufacturers to produce unique elements with geometric freedom. It works without any tooling and, therefore, can significantly reduce unit costs because parts can be produced near the location they will be used, minimising transportation and stock space (Hopkinson and Dickens, 2001 and 2003). In addition, the fact that AM can produce unique elements allows the industry to provide low production volumes and personalised components for products such as footwear, which are economically feasible to the final customer. In the case of footwear personalisation, the technology can benefit not only elite or recreational runners but any individual who wishes to be more active, including sedentary, older people and individuals with gait abnormalities. The personalisation of footwear has the potential to offer the optimal comfort, fit and function properties for a given person. Footwear can be divided into several types (platform shoes, boots, moccasins, etc.), with sport shoes being the most popular. According to the NPD Group Inc (2008), running shoes are the most popular type of sports footwear accounting for 37% of the sales of this type in the U.S.

1.2. Context and origins of the research

"Personalised Sports Footwear: from Elite to High Street" is a five year research project which commenced in October 2006 and concluded in September 2011. It was funded by the Innovative Manufacturing and Construction Research Centre based at Loughborough University, together with the following collaborators: 3D Systems, Glasgow Caledonian University, Liverpool University, New Balance, NTS, MIT, Queens University Belfast, TNO Industries, UK Sport and Xaar (www.lboro.ac.uk/business/e2hs).

The project's main aim was to develop high performance personalised sports footwear using AM to enable affordable fully personalised sports footwear to high street individuals. It was inspired by research at Loughborough University that enabled the manufacture of personalised football boots to reduce injury in elite players using AM (see Palmer (2006) for more details).

The Elite to High Street project is divided into 4 disciplines and 7 work packages, which are summarised in Figure 1.2. Work package 7 (Biomechanics and Podiatry) forms part of the research presented in this thesis and its focus is on personalisation for the high street using AM. To date, the project as a whole has published more than 15 research conference and journal papers (Appendix 1.1) in their respective fields of study.

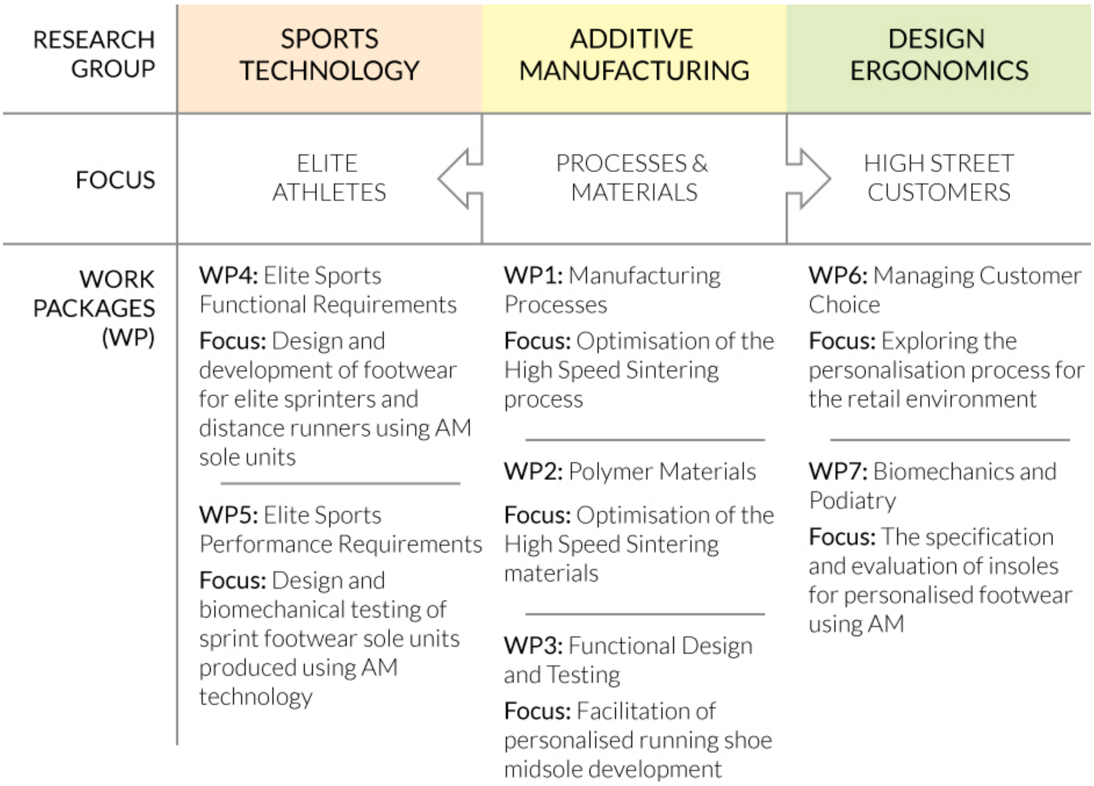


Figure 1.2. Diagram showing summary of the Elite to High Street work packages and their description.

1.3. Aim and objectives

The primary aim of the research presented in this thesis is to develop and explore footwear personalisation using additive manufacturing technology and to evaluate such footwear in terms of comfort and health. Personalised footwear has the potential to tune its properties (e.g. materials and design) to the requirements of the individual to offer optimum comfort and support.

Then, the following research questions were posed:

Q1: 'What are the measurements and foot data needed to specify personalised footwear?'

Q2: 'What design specifications are required for additive manufacturing?'

Q3: 'What are the benefits (if any) of a personalised pair of shoes in terms of comfort and health?'

To address the research questions, the following research objectives were identified.

Objective 1: to develop and explore a process that delivers personalised footwear using additive manufacturing.
Objective 2: to evaluate the short and medium term use of personalised footwear in terms of discomfort and biomechanical variables of the lower extremities.
Objective 3: to develop recommendations and guidance for footwear personalisation.

1.4. Methodology

The methodology consisted of carrying out a systematic review of the literature to determine the gaps and areas that needed further exploration and to identify a possible process for the design and manufacture of personalised insoles using reverse engineering and AM. Once these were established, a pilot study was conducted to explore the feasibility of this process and try out the equipment, materials and techniques (Objective 1). Based on the findings of the pilot study, a longitudinal study was conducted to further explore the personalisation process (Objective 1) and evaluate the personalised insoles in terms of discomfort and biomechanics for a 3-month period (Objective 2). Finally, a case study was conducted with the Biomechanics Research Group at Tuebingen University to explore foot capture using a 'dynamic scanner' (Objective 1). This thesis presents the novel findings, develops recommendations and guidance for footwear personalisation and concludes with suggestions for further research and development together with contributions to knowledge and industry.

1.4.1. Literature review

A critical literature review was conducted and databases were used. Journals, books, theses and conference papers were selected regarding the important topics, for example: footwear and the impact on injury risks; perceived comfort and performance; injuries in runners; measuring techniques for representing and classifying human foot; lower limb abnormalities and footwear fit. The literature review allowed an understanding of the current knowledge, identification of the areas that needed further exploration, and identification of the methods and techniques for the design and manufacture of personalised insoles using reverse engineering and AM

1.4.2. Pilot study

A pilot study was conducted to develop and explore the possible insole personalisation process identified in the literature review (Objective 1). Data were collected from 6 recreational runners during 3 laboratory sessions. Personalised insoles were designed, manufactured using AM and tested in terms of discomfort, performance and biomechanics of the lower extremities. The pilot study also provided the opportunity to refine the research methods used for the longitudinal study.

1.4.3. Longitudinal study

A longitudinal study was conducted to evaluate the short and medium term use of personalised footwear. Thirty eight recreational runners were recruited and matched pairs study design was utilised, with participants divided in two groups: control (shoe + control insole) and personalised (shoe + personalised insole). Participants wore the footwear each time they went running for a 3-month period, completed an Activity Diary after each training session and attended 4 laboratory sessions. Both conditions were evaluated in terms of discomfort and biomechanics of the lower extremities. The results of this study provided guidance for footwear personalisation.

1.4.4. Case study

In order to further investigate the process of footwear personalisation, a case study was carried out with the Biomechanics Group of the Department of Sports Medicine from Tuebingen University, Germany, to explore foot capture using a dynamic scanner for the design and manufacture of insoles using AM. A novel dynamic scanner was utilised to capture the feet of the 4 researchers. Four different insole designs were developed, based on discussion with Tuebingen University. This study contributed to the recommendations and guidance for footwear personalisation (Objective 3).

1.5. Structure of the thesis

The thesis is organised as follows. **Chapter 2** presents a review of the literature, including: biomechanics of running; injury risks in running; running shoes; insoles / orthoses; foot measurements; and footwear comfort. **Chapter 3** presents the literature relevant to the footwear personalisation process, including the development of the process to deliver personalised footwear using AM; common methods to evaluate footwear in terms of comfort, performance and biomechanical variables. This enabled the identification of the main phases, actions, hardware and software required to deliver the personalised insoles that would be tested. **Chapter 4** reports on the pilot study conducted to explore the feasibility of footwear personalisation process and test the materials and methods reviewed in Chapter 3. **Chapter 5** reports on the longitudinal study carried out to evaluate the use of personalised insoles in terms of discomfort and biomechanics for a 3-month period. **Chapter 6** describes the case study conducted in collaboration with the Biomechanics Research Group at Tuebingen University, Germany, to explore capturing the foot using a dynamic scanner for the design and manufacture of insoles using AM. **Chapter 7** discusses the findings of the research as a whole. First, the process of footwear personalisation is approached and methodological considerations are addressed. The findings of this thesis are then discussed in terms of the commercial feasibility and this thesis is concluded with contributions to knowledge and industry together with suggestions for further research and development. Figure 1.3 illustrates the structure of this thesis and how the different chapters relate to each other.

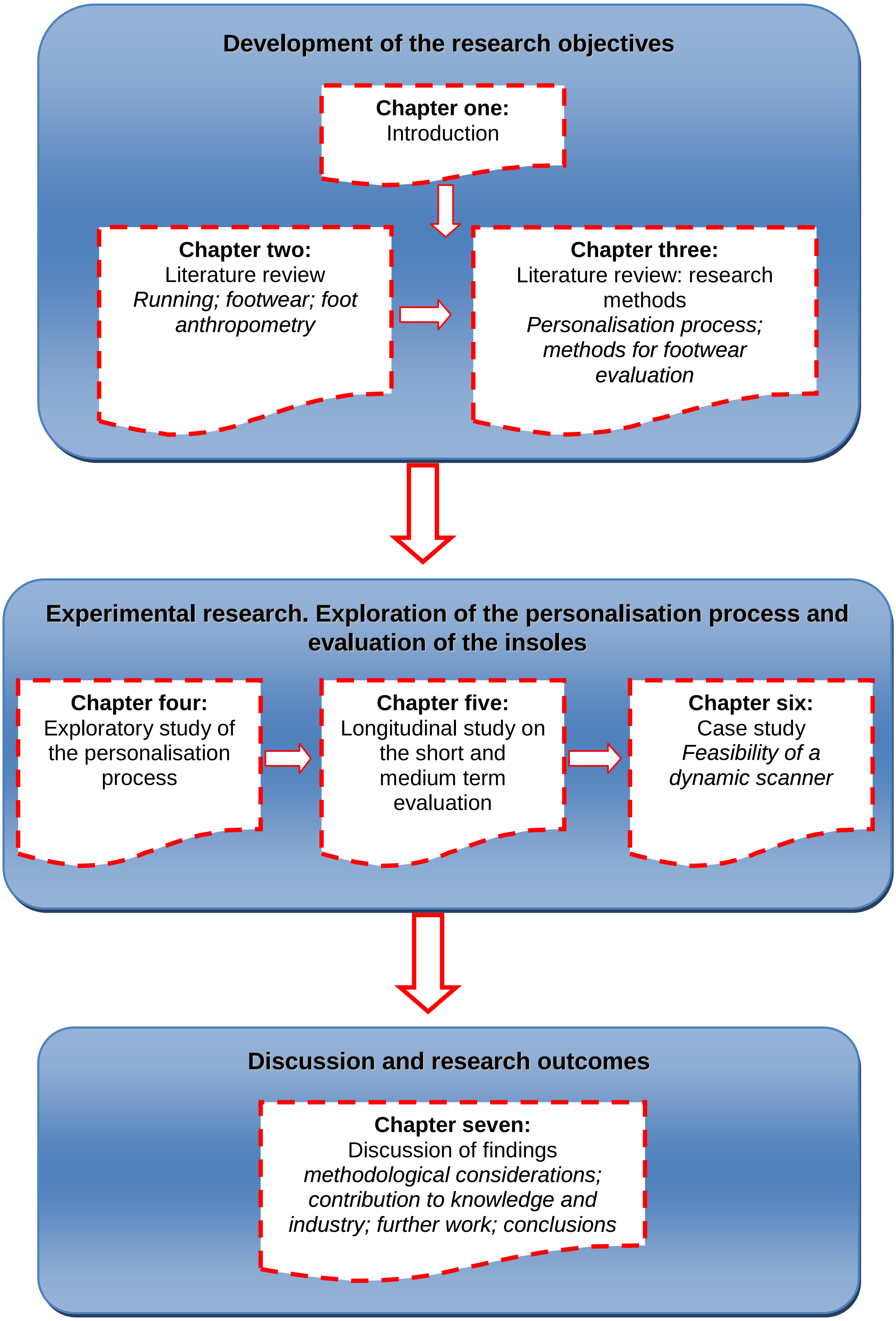


Figure 1.3. Structure of the thesis and how each chapter relates to each other.

Chapter 2: Literature review

2.1. *Introduction*

The literature review has been divided into two chapters. This first chapter's review is related to the biomechanics of running, running shoes, foot anthropometry and biomechanics and footwear personalisation within the scope of this thesis. The second chapter (Chapter 3) reviews technical aspects associated with the methods required for footwear personalisation development using additive manufacturing and its evaluation.

The objectives of this chapter were to:

- understand current knowledge about running, running shoes, foot anthropometry and biomechanics, footwear personalisation;
- identify and critically discuss the current gaps in the scientific literature related to these.

Initially, a broad view was taken of the subject area. Journals, books, theses and conference papers were selected regarding the important topics, for example: use of distinct orthoses/insoles and footwear and their impact on injury risks; self-perceived comfort and performance; injuries in runners and the causes; measuring techniques for representing and classifying human foot, lower limbs abnormalities and footwear fit. Databases such as PubMed, Medline and MetaLib were used and the search strategy focused on keywords: biomechanics of running, running injur*, running shoes, footwear fit, footwear comfort, foot ortho*, insole, foot measur*, foot capture, foot anatomy, footwear evaluation, footwear personalisation, additive manufacturing for customised products and reverse engineering. The references lists from relevant papers were also included in the search. Titles and, if necessary, abstracts were screened for review. Papers were discarded if the methodology was not clear or if the findings were not relevant in the context of this thesis (e.g. footwear for individuals with cerebral palsy).

2.2. *Biomechanics of running*

Running is the most basic and important form of physical activity. It has allowed humans to evolve and was one of the first forms of competition, since the ancient games. Interest in running as a physical activity has been growing and, according to Cavanagh (1989), the victory of Frank Shorter in the marathon at the Munich Olympic Games in 1972 was the catalyst for its increasing popularity in the United States.

During running, the resultant force of each foot contact is around 2 to 4 times body weight, depending on a person's mass, velocity and surface, and foot strikes are between 1,000 to 1,500 per mile (Nigg, 1986; Cavanagh, 1989). These impact forces generate shock waves that are transmitted by the bones of the foot, from distal to proximal, up to the central nervous system (Nigg and Wakeling, 2001). Although these impact *stimuli* have been reported as having a positive effect on bone integrity and tendons (Nigg, 2001), repetitive impact forces from the body to the ground can result in damage to muscle, bones, cartilage and joints, depending on frequency and magnitude (Hreljac, 2004). However, it is speculated that impact signals can be altered according to the shoe/surface interaction as well as biomechanics of running and speed (Boyer and Nigg, 2007). According to the point of application and direction, these external forces cause tension, torsion, compression, bending and shear (Nigg, 1986).

In order to protect the lower limbs, runners tend to adapt their lower extremity and absorb impact, sometimes changing foot and leg geometry (e.g. flexing the knee or dorsiflexing the ankle), increasing the stiffness and muscle activity in accordance to the type of surface they are landing and on the magnitude of the forces (McKenzie *et al.*, 1985; Nigg, 2001). Since runners have distinct areas of the foot with which they make first contact with the ground, the term "foot strike index" was introduced, allowing the classification of runners as rearfoot, midfoot or forefoot strikers (Cavanagh and Lafortune, 1980). To calculate this index, a straight line is drawn from mid-heel to mid-toe along the longitudinal axis of the foot (Miller, 1990). If the centre of pressure at initial foot contact lies in the rear third of the foot, the runner is classified as rearfoot striker, if it is in the middle third or in the front third, the runner is classified as midfoot or forefoot striker, respectively. Rearfoot strikers exhibit a peak force (called impact peak) early during ground contact (or stance phase) after the touchdown of the heel on the ground that rises up to 2.9 times bodyweight (Figure 2.1) and can cause greater stress on rearfoot (i.e. heel) region (Cavanagh, 1980; McKenzie *et al.*, 1985).

Forefoot strikers are more associated with sprint runners and do not present the same (sometimes it can be absent) impact peak force as rearfoot strikers (McKenzie *et al.*, 1985; Williams III *et al.*, 2000). For long distance runners, Williams and Cavanagh (1987) established relationships between biomechanical aspects and running economy in 31 individuals and found that rearfoot strikers are more economical than individuals that have their first contact mid or forefoot.

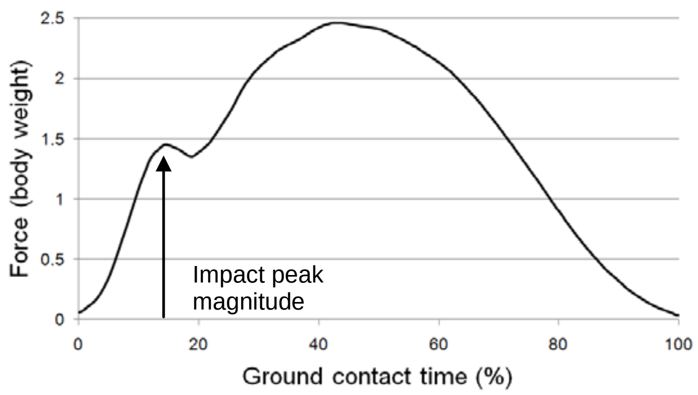


Figure 2.1. Example of a vertical ground reaction force of rearfoot strikers during running.

2.2.1. Foot anatomy

The human foot has bones, muscles, ligaments and tendons. It supports the whole body maintaining balance forward and backwards, is composed of 26 bones and has adapted to enhance weight bearing capacity and to allow the attenuation of the vertical forces whilst in locomotion (Hawes *et al*., 1994; Cheng and Perng, 1999). The foot and ankle have triplanar motion: adduction/abduction (transverse plane), dorsiflexion/plantar flexion (sagittal plane) and inversion/eversion (frontal plane) (Donatelli, 1996). Movement by the ankle joint will be transferred to the tibia and knee.

The foot is often divided into three sections (Figure 2.2):

1. Rearfoot. Responsible for mid and forefoot movement in transverse and sagittal planes, but not in the frontal plane (Pohl *et al.*, 2006) and is composed of the talus and the calcaneus. The talus makes the connection between the foot and leg (ankle joint), while the calcaneus is the biggest bone of the foot and is where the Achilles tendon is attached. Also, under the calcaneus bone there is a fat pad which is a good energy absorber (Cavanagh *et al.*, 1984).
2. Midfoot. Responsible for stability of the foot and sends movements from the rear to the forefoot. It constitutes the navicular, cuboid and cuneiform bones (Donatelli, 1996).
3. Forefoot. Adapts to uneven surfaces and constitutes the metatarsals and phalanges (Donatelli, 1996).

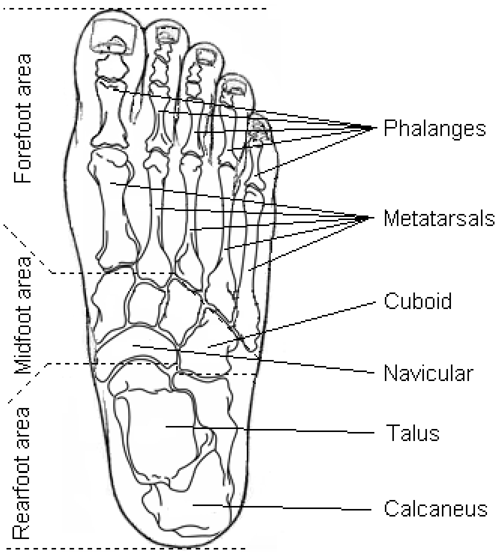


Figure 2.2. Representation of the three sections of the foot and the main bones.

The subtalar joint (also called 'talocalcaneal') is formed by the talus and calcaneus bones. It is the major joint of the foot, together with the midtarsal joint (Smart *et al.*, 1980). In a situation where the subtalar joint is inverted, the ankle is plantar flexed and the foot is adducted, 'supination' occurs. Pronation occurs with eversion of the subtalar joint with ankle dorsiflexed and the foot abducted. Therefore, the term supination or pronation corresponds to the tri-planar motion of the subtalar joint, as shown in Figure 2.3 (McNicol *et al.*, 1981).

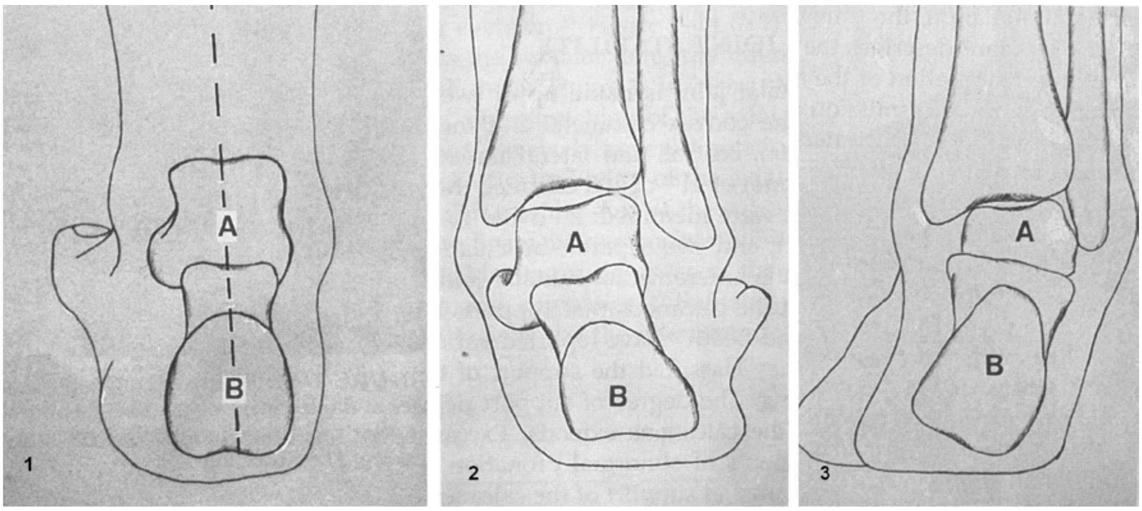


Figure 2.3. Positions of the subtalar joint: 1 – neutral; 2 – pronated; 3 – supinated. A = talus; B = calcaneous (from Donatelli, 1996).

The medial longitudinal arch (MLA, or simply referred to as 'arch') is a spring structure which is crucial for locomotion. Its elastic property is capable of storing strain energy together with the Achilles tendon making running more energy efficient (Ker *et al*., 1987). According to Alexander (1987), a long distance runner stores elastically 17 joules in the arch of the foot and 35 joules in the Achilles tendon. Cavanagh and Rodgers (1987) described the MLA as one of the most important and most variable structural characteristics of the foot. It allows the foot to change shape dynamically and in accordance to the amount of weight loaded (Cheng and Perng, 1999). Hence, arch type has an important role in the development and prevention of injuries, which will be evidenced further in this thesis. The arch types often described in the literature are: high arch (cavus foot type), normal and low arch (flatfoot), as illustrated on Figure 2.4 (Cheskin *et al.*, 1987).

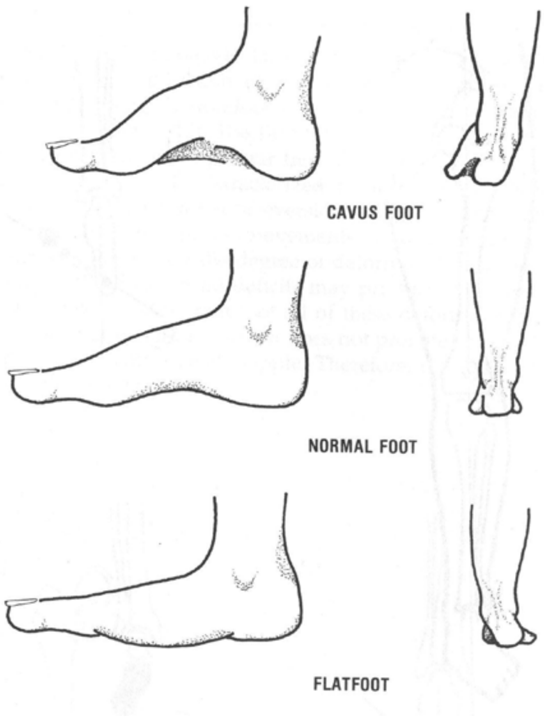


Figure 2.4. Representation of the 3 types of foot: cavus, normal and flatfoot (from Donatelli, 1996).

The arch is constituted by the bones: calcaneus, talus, navicular, cuneiforms, and the first, second, and third metatarsals. The anthropometric measurements and values that classify the foot in cavus, normal or flatfoot are described on Section 2.4.3.

2.2.2. Leg musculature

The leg consists of skeleton and muscle groups, such as: the hamstrings (semitendinosus, semimembranosus and biceps femoris), triceps surrae (gastrocnemius, soleus and plantaris), quadriceps (vastus lateralis, vastus medialis, vastus intermedius and rectus femoris) and tibialis anterior. Tibiais anterior has as a major role in dorsiflexing the foot before heel strike and reducing the plantar flexion movement of heel-strike (von Tscharner *et al.*, 2003). The objective of the leg musculature prior to landing is to stabilise the joints of the leg, ankle and foot to attenuate any soft tissue vibrations resulting from impact with the ground (Mundermann *et al.*, 2004). Body musculature adjusts the joint torques and stiffness for take-off based on input signals that produce soft tissue vibrations experienced from previous interactions with the ground (Nigg and Wakeling, 2001). These soft tissue vibrations are not comfortable and would cost energy, so the muscle acts to avoid it by using what has been defined as ‘muscle tuning’ strategy (Nigg, 2001).

2.2.3. Injury risks in running

Injury has been defined in the literature as the equivalent to the failure of a machine or a structure (Bahr and Krosshaug, 2005). Injuries in running are more frequently categorised as musculoskeletal ailments of the lower limb that require runners to do stoppage training or induce them to reduce the weekly distance covered (Hoeberigs, 1992; Lun *et al.,* 2004). There is still a lack of agreement in the literature about the determination of injury and/or site (lower extremity injuries, headache, fatigue and others), which makes the comparison between studies, difficult (van Gent *et al*., 2007). Injuries can be due to extrinsic factors (e.g. training errors, poor footwear, running surface, level of competition, environment), intrinsic factors (e.g. poor flexibility, malalignment, anthropometry, previous injury, running experience, motivation, poor physical fitness) or a combination of both (Parkkari *et al*., 2001; Tauton *et al*., 2002). In most cases, the development of an injury is a combination of these. It is well established in the literature that the knee is the predominant site for running injuries (more than 40%), followed by the tibia, the foot/ankle, the back and hip (Wen *et al.*, 1997; Tauton *et al*., 2002; van Gent *et al.*, 2007). The knee is generally more vulnerable to injures, because this joint usually flexes, “adjusting” or compensating for any malalignment or abnormality in the lower limbs (Frederick *et al.*, 1983).

According to several authors, during gait a normal sequence of the subtalar joint is the following (Figures 2.5 and 2.6) (McNicol *et al.*, 1981; Clarke *et al.*, 1983b and 1984; Cavanagh, 1989; van Woensel and Cavanagh, 1992; Kilmartin and Wallace, 1994):

- the foot supinates (turning the bottom of the foot away from the body’s midline) around 2º when the heel touches the ground (first 10% of foot contact);
- the foot pronates around 4º during the midstance phase (around 50% of foot contact) and the tibia rotates internally; and

- the foot supinates again, thereby locking the midtarsal joint and transforming the foot into a rigid lever until takeoff.

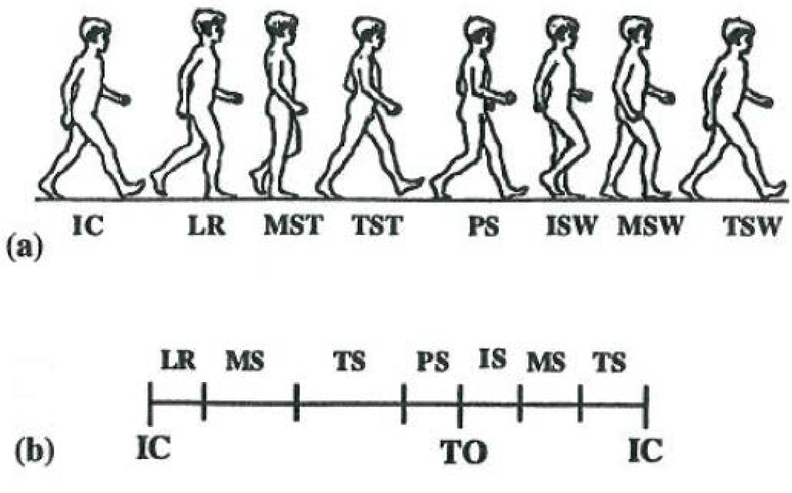


Figure 2.5. The gait cycle. (a): walking figure. (b): *IC, initial contact; LR, loading response; *TO, toe off; MS, midstance; TS, terminal stance; PS, preswing; IS, initial swing; MS, midswing; TS, terminal swing. Adapted from Novacheck (1998).

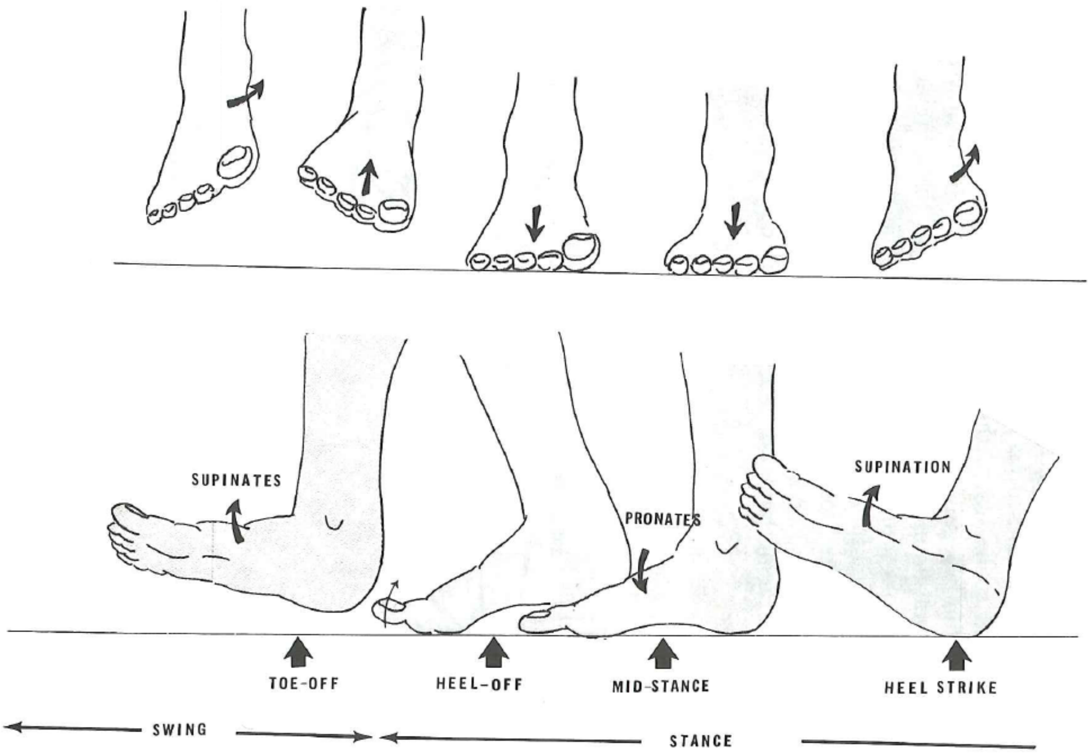


Figure 2.6. Foot during the stance phase (from Cailliet, 1983).

Supination 'locks' the midtarsal joint creating a very stable foot whereas pronation 'unlocks' the midtarsal joint making the foot flexible, capable of adapting to any type of surface (McNicol *et al.*, 1981). A small amount of pronation and supination is essential for the foot to adapt, absorb impact and compensate any leg/foot abnormality or surface problem, and this adaptation will be emitted to the tibia as tibial rotation (Smart *et al.*, 1980; Eslami *et al.*, 2007). Foot movement is transferred by a coupling mechanism from the calcaneus to the tibia which externally or internally rotates (van Woensel and Cavanagh, 1992; Stacoff *et al.*, 2000; Ferber *et al.*, 2005). Hence, the amount of tibial rotation is speculated to be linked with a rearfoot/forefoot coupling motion (Eslami *et al.*, 2007).

The amount and timing of pronation is affected by the foot structures and the speed of running, among other factors (van Woensel and Cavanagh, 1992). Foot eversion refers to the movement of the ankle in the frontal plane and, being a component of pronation, it is often assessed to predict the amount of this movement. Excessive foot eversion is linked to shin splints, stress fractures, and Achilles tendinitis, by forcing the tendon to bend laterally, producing asymmetric stress distribution (Clarke *et al*., 1984; Stacoff *et al.*, 2000). Excessive pronation can also occur as a compensatory result from anatomical abnormalities such as: lack of muscle strength, tibia vara, forefoot varus, and leg discrepancy, to cite a few (Hintermann and Nigg, 1998).

Although excessive pronation is considered to be one of the most frequent reasons for injury in runners, other variables are also linked to lower limb damage, for example injurious running patterns. Excessive vertical loading rate, impact and active peak, among others, have been also linked with injury in runners (Milner *et al.*, 2006). The hypothesis is that high values at high rates of vibration (shock waves) produced by the ground reaction force (GRF), which are then transmitted through the musculoskeletal system to the rest of the body, have a detrimental effect on the body (Miller, 1990). Vertical loading rate is the vertical impact force with reference to time and is usually presented as the maximum or average value in Newtons or body weights per second (bw/s) (Miller, 1990). The other variable is the vertical impact peak, defined as the first peak in the vertical component of the GRF as shown in Figure 2.1. Vertical loading rate is more associated with tibial stress fractures (Milner *et al.*, 2006) whereas vertical impact peak is linked with overuse running injuries of the musculoskeletal system in general (Miller, 1990; Hreljac *et al.*, 2000). Overuse injuries happen when the structure is exposed to a high number of repetitive forces, resulting in a fatigue effect over a period of time beyond of the structure's capabilities, cumulating in micro-traumas: stress fractures, tibial stress, cholndromalacia pattelae, plantar fasciitis and Achilles tendinitis are all classified as overuse injuries (Hreljac *et al.*, 2000). For these reasons, research has been conducted to analyse the effects of various types of insoles and footwear on biomechanical variables like GRF and the movement of the ankle and knee (Mundermann *et al.*, 2003b; Nigg *et al.*, 2003; McMillan and Payne, 2008).

Apart from the causes already discussed, it appears from the literature that foot type is also a useful indicator of predisposition to injury. In fact, foot arch morphologies are considered the most common misalignments associated with running injuries, as each arch type has its own properties for storing and returning energy. Hence, the biomechanical attributes of each foot arch will determine the type of injuries it is exposed to.

As mentioned earlier in this chapter, the foot is often classified into normal, low and high arched, with the latter two being more associated with injuries. The flatfoot usually has more spread of plantar pressure by having greater contact with the ground. According to Williams III *et al.* (2001a) from a study which recruited 40 runners (20 high and 20 low arched), low arched runners tend to have greater rearfoot eversion, eversion/tibial internal rotation ratio (EV/TIR)[1], eversion excursion and eversion velocity in comparison with high arched runners, and this greater ratio leads to more foot, back and knee injuries.

The high arched foot is characterised by the longitudinal arch being more rigid and not so flexible, which makes it less efficient at absorbing impact shocks. The contact area with the ground tends to be reduced and be more lateral in comparison to other types of foot (normal and flatfoot). The lateral contact leads to supination of the foot, high lateral loadings and high peak pressures (Cavanagh, 1980; McKenzie *et al*., 1985). Therefore, high arched runners tend to have more foot and ankle injuries (Williams III *et al*., 2001b), although Cowan *et al.* (1993) also reported that high arched feet have an increased risk of knee overuse injury. In addition, high impact peaks, like the ones produced by a high arched foot during running, are associated with greater risks of injury, especially tibial shock, and mechanical trauma (Williams III *et al*., 2001a).

Recently, the arch classification has also been reported as a good indicator for determining individual preferences in terms of comfort. Mundermann *et al.* (2001) recruited 206 military personnel reported that people with a high arch tend to prefer softer inserts and more cushioning, whereas low arched individuals tend to prefer

[1] An EV/TIR is calculated dividing the excursion of eversion by that of tibial internal rotation, over the time period occurring on midstance (Ferber *et al*., 2005).

harder insert materials and thus, less cushioning. However, more evidence is needed to confirm or reject this relationship. Methods of foot type classification to characterise individuals are explained in Section 2.4.3.

2.3. Running shoes

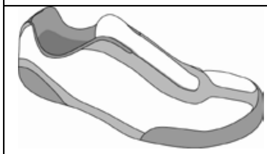
Footwear is the most important accessory for a runner. It will intermediate the relationship between the foot and the ground, being able to reduce (but in a few cases, increase) the injury risks previously mentioned. Lower limb structures depend on many factors and some of them are substantially influenced by the shoe type (Hintermann and Nigg, 1998). According to Nigg and Segesser (1992) and McPoil (2000), footwear has several aims to runners:

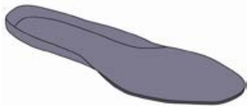
- protection for the foot against hot, rough or rocky surfaces;
- traction for different terrains (asphalt, wet floor, and so on);
- motion control, specially heel stabilisation and midfoot support;
- cushioning for attenuating excessive load;
- improvement of performance; and
- comfort to the runner to be able to maintain aerobic work for a prolonged time.

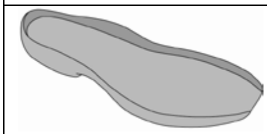
The first four of these aims are related to the reduction of the risks for injury. Footwear can be efficient in decreasing the magnitude of impact force intensity by about 33% in comparison with walking barefoot (Clinghan *et al*., 2007). For instance, cushioning, the terminology used for reduction of the impact peak force, can protect the body from chronic overloads by reducing the impact force loading rate, spreading it to a larger area and altering post heel strike muscle activity (Shorten, 1993; Wakeling *et al*., 2002). The four main parts of running footwear are described in Table 2.1.

Table 2.1. Running footwear's main parts and their description. Illustrations adapted from Head (2010).

Part	Description


Upper
	• Description: covers the dorsal aspect of the foot and has a breathability component.
	• Main objectives:
	  • to stabilise the subtalar joint via the heel counter, located on the rear part (McKenzie *et al*., 1985);
	  • to provide passive control of foot temperature and humidity and protection of foot and ankle (Hawes *et al*., 1994);
	  • the tongue (part of the upper) protects the dorsal part of the foot from the laces and eyelets;
	  • the toe box should allow toes to dorsiflex and plantar flex whilst a person is walking or running (McKenzie *et al*., 1985).
	• Material: leather or nylon or a mixture of both.

 Insole	The basic role of an insole is to provide cushioning for the runner, but it has less shock attenuation because is thinner in comparison to a midsole. A detailed description, objectives, characteristics and materials will be reported in Section 2.3.1.


Midsole
	• Description: the main part of the shoe, where most of the technology and research is applied to.
	• Main objective:
	  • to provide cushioning for impact sock attenuation, spread plantar pressure into a wider area and return energy.
	• Characteristics:
	  • can be manufactured via compression or injection moulding techniques (McPoil, 2000);
	  • must be capable of returning to its original shape as quick as possible after being deformed in order to not lose too much energy (McPoil, 2000). Shorten (1993) correctly indicated that the work done by the midsole can be called 'output energy' and the work done on the midsole 'input energy'. However, too soft midsoles can induce individuals to pronate more than normal (Hamill and Derrick, 1996). Likewise, too hard midsoles act as orthotics, preventing individuals pronating the foot (Hamill and Derrick, 1996).
	  • Midsoles must be flexible under the MPJ to allow the foot to bend over this joint (Smart *et al*., 1980);
	  • comfort and performance aspects confine the thickness and properties of the midsole to a set range (Shorten, 1993).
	• Materials: elastic ones – ethylene vinyl acetate and polyurethane (Kinoshita and Bates, 1996). According to Alexander (1987), the foot needs an elastic material to cushion the impact with the ground, but not a shock absorber unless the aim is to minimise the tissue vibrations.


Outsole
	• Description: is the part of the shoe that contacts the ground.
	• Main objectives:
	  • to serve as an arch bandage to prevent twisting;
	  • to act as a stabilisator by providing reinforcement on the midfoot right below the foot arch (McKenzie *et al*., 1985);
	  • to provide traction in accordance to the terrain (McKenzie *et al*., 1985).
	• Common material: rubber.

With the goal of reducing injures, the sports industry currently markets two main types of running shoes: motion control and cushioning training. Motion control shoes focus on accommodating low arched feet individuals who overpronate and weigh more than 100kg. In comparison to cushioning shoes, they are more efficient at reducing rearfoot motion: peak eversion and eversion excursion (Butler *et al*., 2006). Also, they provide stability, which is essential to the runner to avoid twists and attenuate any leg/foot problem (Bahlsen and Nigg, 1987; Stacoff *et al*., 2001). On the other hand, cushioning shoes are designed for high arched and supinator feet and tend to reduce tibial shock and vertical loading variables (McPoil, 2000; Butler *et al*., 2006).

The optimal shoe should quickly return to its original shape after load application during landing (Nigg and Segesser, 1992; Shorten, 1993). This capability allows the energy generated in the first half of the stance phase to be stored. If a shoe is very soft it can be compressed very fast, exposing the foot to high loading amplitudes (Nigg *et al*., 1986). Shoe stiffness is a relevant property because optimal hardness is capable of returning the generated energy to the joint (that is, less energy is lost) and hence improving performance (Stefanyshyn and Nigg, 2000).

According to Marti (1989), shoe selection for a runner involves three main criteria (1) orthopedically correct construction of the running shoe; (2) fit/comfort; and (3) slip-resistance/profile of sole. Despite all the benefits of footwear to the runner, it is important to emphasise that if it is not correctly selected, there is an increased risk of running injuries. Running shoes decrease sensory perception, which can lead runners to underestimate the magnitude of impact loads on the plantar surface and, as a consequence, increase their workout (McPoil, 2000). By increasing workout, muscle activation is altered, inducing individuals to early fatigue and/or injury. Shod humans rely on muscle receptors instead of tactile receptors of the foot, probably because the shoes make tactile information less available by attenuating local deformation (Robbins and Waked, 1998). Also, studies suggest that there is an association between closed-toe shoes worn in childhood and a flat foot, with unshod children having less prevalence of flat feet (Rao and Joseph, 1992; Sachithanandam and Joseph, 1995). A recent report from Lieberman *et al.* (2010) suggests flat foot can happen because many running shoes have arch support and stiffened soles that may lead to weaker foot muscles, reducing arch strength. Therefore, footwear is likely to inhibit the development of a normal or high arched foot.

2.3.1. Insoles/Orthoses

According to McKenzie *et al.* (1985), biomechanical abnormalities are the fourth most common problem that leads runners to injury. For instance, when an individual has any excessive foot/leg problem, the doctor, podiatrist or clinician may prescribe an orthosis to restore normal arrangement. The specific reasons why runners start using orthoses may vary, but knee and foot pain are by far the most common complaints and account for 80% of cases; ankle, shin, hip and other types of pain are also cited (Gross *et al*., 1991). According to Gross *et al.* (1991), excessive pronation is the most frequent problem (31.1%) that leads runners to use orthoses, followed by plantar fasciitis (20.75%). Achilles tendinitis, excessive quadriceps (Q) angle, leg length discrepancy, patellofemoral disorders and shin splints must also be considered. Razeghi and Batt (2000) reported that leg length discrepancy and rearfoot pronation are problems that an orthosis corrects most effectively. In the case of restricting rearfoot pronation the orthosis provides a lift for the heel, reducing ankle dorsiflexion, which is suggested to be a component of pronation (Clarke *et al*., 1984). Generally speaking, a custom made orthosis also increases the plantar contact area, redistributing the force, reducing peak pressure values (Razeghi and Batt, 2000).

However, the topic is still very controversial and the concept of lower extremity malalignment being correlated to injuries is not unanimous. Although there are many reports in the literature indicating that foot orthoses may indeed reduce eversion and tibial rotation, other studies do not agree that static alignments are related to injuries. Table 2.2 summarises examples in the literature on the effectiveness of orthotics and lower limb alignment related to running injuries and evidences the contradiction with regards to the effectiveness of foot orthosis on realigning the skeleton and reducing the pain and injury occurrence. This discrepancy in the literature can be due to the fact that overuse injuries are usually a combination of different factors, as exposed in Section 2.2.3: extrinsic (e.g. training errors, poor footwear, running surface, level of competition, environment), intrinsic factors (e.g. poor flexibility, malalignment, anthropometry, previous injury, running experience, motivation, poor physical fitness) or a combination of both. When only one factor is analysed (e.g. lower extremity static alignment) it does not provide the full picture of the causes of an injury for the individual. According to Gross *et al.* (1991) complaints during orthotic usage have been attributed to a poorly fitted and badly fabricated orthosis or poor diagnosis. Nevertheless, no studies have reported any negative effects regarding the use of orthoses. Kilmartin and Wallace (1994) argued that it may be the case that individuals just remove any uncomfortable or damaging insoles. Analysing the literature, it appears that an orthosis will not correct all of the problems associated with biomechanical variables, but many treatments with an orthoses or insoles (around 75%) are shown to have been successful (Nigg *et al*., 1999).

Table 2.2. A descriptive summary of examples in the literature about the effectiveness of orthotics and lower limb alignment related to running injuries.

Author(s)	Main aim	Design	Sample	Main finding
Gross *et al.* (1991)	To assess the effectiveness of orthotic inserts in the distance runner.	Retrospective (using questionnaires)	347 runners that have previously worn orthotics or still use them.	Orthotic was effective in providing symptomatic relief in the long distance runner.
Kilmartin and Wallace (1994)	To examine the scientific support for the use of biomechanical foot orthoses in sports medicine.	Literature review	Search strategy or the number of papers reviewed not indicated.	Orthoses are clinically useful in the treatment of some sports related lower limb injuries.
Wen *et al.* (1997)	To examine retrospectively the relationship between lower extremity alignment and risk of overuse injury in runners.	Retrospective (using questionnaires)	304 runners enrolled in a marathon training program.	Lower extremity alignments, such as: arch index, leg length discrepancy, knee varus and so on, are not a major factor for overuse injury in runners with low mileage (around 12 miles/week).
Stacoff *et al.* (2000)	To quantify the effects of medial foot orthoses on skeletal movements of the calcaneous and tibia during the stance phase in running.	Repeated measures	Five injury free males.	Orthotic effects are subject specific and unsystematic across conditions.
Nigg (2001)	To discuss the possible association between impact forces and foot pronation and the development of running related injuries.	Critical analysis of the literature	All papers published over the last 25 years on the topics of: kinematics, kinetics, resultant joint movements and forces, muscle activity, subject and material characteristics, epidemiology, and biologic reactions.	The experimental results did not provide any evidence for the claim that shoes, inserts, or orthotics align the skeleton.
Mundermann *et al*. (2003a)	To quantify the effects of posting and custom-molding of foot orthotics on lower extremity kinematics and kinetics during running.	Repeated measures	21 recreational runners with no history of lower extremity injuries.	Foot orthotics has the potential to reduce pain and injury.
Lun *et al.* (2004)	To determine if measurements of static lower limb alignment are related to lower limb injury in recreational runners.	Prospective	87 recreational runners followed-up for six months.	No evidence that static biomechanical alignment measurements of the lower limbs are related to lower limb injury except patellofemoral pain syndrome.
Stackhouse *et al.* (2004)	To compare the differential effect of custom orthoses on the lower extremity mechanics of a forefoot and rearfoot strike pattern.	Repeated measures	15 runners with no history of orthotic use and were injury free.	Foot orthoses do not differentially affect rearfoot motion of a rearfoot strike and a forefoot strike running pattern.
Ferber *et al.* (2005)	To compare joint coupling patterns and variability of the rearfoot and tibia during running in subjects who were treated with two types of orthotic devices to that of controls.	Repeated measures	11 runners with lower extremity injuries.	Foot orthotic devices do not produce significant changes in rearfoot inversion/ eversion and tibial internal/external rotation joint coupling pattern, which was thought to be the a component of the relief experienced with the orthotic use.

To date, no standard procedure for the prescription or manufacture of an orthosis has been found. Likewise, there is still no agreement regarding the best shapes of insoles and they seem to be designed with little scientific baseline data. The types of shapes used include: custom molded, posted, a combination of both, high/low arch and spherical (Landorf and Keenan, 2000). In terms of materials, orthoses are categorised as soft, semirigid, rigid, elastic and viscous, and the optimum is specific to each person (Sperryn and Restan, 1983; Neale and Adams, 1985). This is evidenced by Nigg *et al.* (1998), where they compared elastic (harder) and viscous (softer) inserts and found that oxygen consumption of the runner for both was dependent on individual characteristics. In most cases, the more severe the pronation, the more rigid the material required. According to Neale and Adams (1985), materials used can be rigid plastics (e.g. polypropylenes), semi-rigid plastics (e.g. suborthylene and hexcelite) or flexible plastics (e.g. aquaplast and mixtures of cork/latex). Apart from plastics, other materials such as acrylics, foams, leathers and corks are less frequently used (Nicolopoulos *et al*., 2000). On top of that, wedges or posts are then applied anteriorly or posteriorly, according to the degree of deviation (Sperryn and Restan, 1983).

In addition to correcting biomechanical problems, inserts can improve sensory feedback, comfort and performance. A recent study conducted by Nurse *et al.* (2005) found that textured inserts decrease muscle activity as well as the torques generated by the knee joint in comparison with smooth inserts. This decrease in both variables may be due to the increased sensory feedback that the textured insert provides. Evidence of how an insert may improve performance can be demonstrated by considering a person with poor alignment of the lower limbs, such as leg length discrepancy. The individual is induced to compensate for this with extra muscle work (Nigg, 2001), implying a decrease in performance. Therefore, correcting the lower limb may lead to an improvement in performance. Indeed, a number of articles suggest that orthoses are good for improving performance, by reducing muscle work and increasing self-perceived comfort (Mundermann *et al*., 2001). Also, according to Stefanyshyn and Nigg (2000), bending stiffness of the insole decreases the amount of energy absorbed at the metatarsophalangeal joint (MPJ) which leads to a positive effect on performance. However, future studies must be conducted in order to determine the optimal orthoses (its shape, material, hardness) for a given person's characteristics (e.g. weight, preference for comfort, alignment and muscle strength).

Making comfortable orthoses is important, as it will determine whether a person will keep using them for a long period. The work done by Sperryn and Restan (1983) confirms the possibility of runners dismissing their use. Their study prescribed orthoses for 50 patients and, after 3.5 years, only 54% were still using them. Doctors should advise runners that there is a period of adaptation and that they may feel a bit awkward with the device in the first instance. It is suggested that orthoses counteract the preferred movement path and, as a consequence, muscle activation increases to maintain the preferred movement path (Mudermann *et al*., 2003b). Therefore, it is expected that using an orthosis for a long period will incur in changes in the preferred movement path leading the orthotic to the 'optimal' condition for comfort and performance. Likewise, according to Nigg *et al.* (1999), the optimal orthoses reduces muscle activity, making it feel more comfortable and increasing performance.

2.3.2. Footwear fit

Many studies have indicated that fit is the basic yet most important component of footwear not only because it is strongly correlated to comfort, but also 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 the footwear if it is poorly fitted and this can start to damage the tissues (Chantelau and Gede, 2002). According to Cavanagh (1980), fit is considered as being the main factor that an individual take into account when evaluating shoe comfort.

Fitting the foot well, according to McPoil (2000), means that the footwear is extremely similar to person's shape of the foot. In other words: "a shoe fits when the dimensional profile and sections of the shoe correspond to the dimensional profile and sections of the foot" (Rossi, 1988). Hence, ideally, the inside of the footwear should match the exact shape of the foot, which traditionally involves the construction of a shoe "last". The last, made of metal, plastic or wood, is a model of the human foot on which shoes are constructed and is considered as the 'heart' of the shoe, because it will determine the shape, size and dimensions of the footwear (Cavanagh, 1980; Cheskin *et al*., 1987). Thus, the last is a generic reference that intends to reproduce the human foot, but every person's foot has a unique anatomy. Although almost 30 measurements are taken for a shoe last to be designed (discussed in Section 2.4), when an individual goes to purchase footwear, the only two measurements taken into account are length and width. However, these two measurements alone are unlikely to achieve a good fit and others seem to be crucial, including instep girth, bottom width, heel height, toe box space and so on (Goonetilleke *et al*., 1997; Cheng and Perng, 1999; Witana *et al*., 2004). Furthermore, many shoes are sold over the internet and catalogues without any previous fitting! Although the dimensions of a shoe last vary (or at least should vary) according to the foot morphology of a specific population (Kouchi, 1995; Mauch *et al*., 2008), the methodology for designing lasts is not well documented or standardised (Bunch, 1988). Houston *et al.* (2006) report that US military and commercial footwear use straight linear regression approximation for their data leading to poor fit. They suggested that the last should be wider at the heel or at the ball. Moreover, Freedman *et al.* (1946) indicated that some sole dimensions of shoe lasts are determined by taking into account only the weight bearing portions of the foot.

Most countries have tried to standardise shoe size: for the British shoe size scale, every inch in length corresponds to three full sizes (or six sizes if halves are considered), whereas for the French scale, every size corresponds to 1/3 of a centimetre (Rossi, 1988; Xiong *et al*., 2008). In a broader attempt to standardise the system of sizing shoes for all countries, the International Organization Standardisation proposed a system known as Mondopoint, in which measurements of the length and width of the foot in millimetres are used to indicate the appropriate shoe (ISO 9407, 1991). For example, an individual with a foot length and width of 260 mm and 99 mm respectively, will have a shoe size 260/99. This system was adopted in Korea and by some organisations around the world, but not officially by any other country. Despite efforts to standardise the sizing system, length and width values do not increase with the same ratio, nor does foot height and length (Cabrera *et al*., 2004; Xiong *et al*., 2008). In addition, due to variations in style, materials used, sole thickness and so on, some shoe sizes do not fit exactly the same for all brands and models (Rossi, 1988). However, the upper material usually allows a certain level of adjustment, moulding on the wearer's foot and thus providing better fit (Hawes *et al*., 1994). Finding the shoe with a good fit is not an easy task.

Despite efforts to collect anthropometric measurements, most footwear brands offer only one width per shoe size and, because it is unlikely that individuals would tolerate too tight dimensions, the errors in footwear fit are suggested as being up to +33 mm (Houston *et al*., 2006). Proper fit requires a good understanding of the total 3-D shape of the foot, or at least two dimensions in each region: forefoot, midfoot and rearfoot (Goonetilleke *et al*., 1997; Goonetilleke and Luximon, 2001). Fit can also affect performance. For example, if the axis of the foot does not match that of the shoe, then the individual has to flex the shoe against additional resistance (Hawes *et al*., 1994). The most recommended, yet costly, way of achieving a good fit would be to produce customised lasts for every consumer (Luximon *et al*., 2003). In a recent study, Leng and Du (2005) reported a method for delivering customised shoe last based on the individual's foot captured using a laser scanner and existing last models. Although the method shows potential, it lacked financial details, like costs of implementing such a system in retail stores.

2.4. Foot measurement

In order to specify footwear with a good fit, it is imperative to understand the characteristics, dimensions and properties of the foot. Methods of taking anthropometric measurements of the human foot have been investigated throughout the years. In forensic investigations, footprints (foot length and width) are often associated with stature and gender to estimate the identity of individuals (Gordon and Buikstra, 1992; Ozden *et al*., 2005). In most of the studies, however, the collection of anthropometric measurements of the foot serves as a reference for footwear companies. Reports documented in the literature include: Dahlberg and Lander (1948), Baba (1975), Hawes and Sovak (1994), Kouchi (1995), Ashizawa *et al.* (1997), Luximon *et al.* (2005) and Mauch *et al.* (2008).

When designing shoes, it is important to consider population groups separately as foot shape varies significantly (Kusumoto, 1990). Dimensional differences according to ethnicity have been reported by Baba (1975) in a study that recruited a total of 1844 Japanese from 18 to 40 years old. They compared the foot measurements of their sample with another study and concluded that Japanese males have larger ball girth and broader foot in comparison to French males for the same foot length. Likewise, Hawes *et al.* (1994) compared 11 measurements between 708 of Caucasian North Americans and 513 Japanese/Korean male subjects and identified small differences in the height of the hallux and the location and angularity of the MPJ axis between North American and Japanese/Korean population. According to Cheskin *et al.* (1987), the human foot can be also classified by race. They reported that the oriental foot tends to be short and broad in the forepart of the heel and the toes are straight with a large space between the big and second toes; that the Caucasian foot is an equal mixture of high, normal and low arches; and finally, that the negroid foot is broad in the forepart and narrow in the heel, with the toes flared out to straight. When comparing the ethnicity directly, the black male population have consistently larger foot length, breadth and girth measurements systematically throughout the foot (Freedman *et al*., 1946). There are also differences in foot proportions between men and women (Krauss *et al*., 2008). Women have larger calf and ankle circumferences, a higher foot arch, shallower first toe, shorter ankle length, narrower foot breadth and smaller ball girth than males for the same foot length (Baba, 1975; Wunderlich and Cavanagh, 2001; Krauss *et al*., 2008). Even between populations of regions in the same country, differences can occur (Kalebota *et al*., 2003). In Sweden, for instance, it has been suggested that populations from cities are taller and have bigger feet than people from rural areas (Dahlberg and Lander, 1948). Dahlberg and Lander (1948) speculated that this difference is not due to nutrition, once urban individuals are also leaner. They later suggested that this difference is because in urban areas the population is more mixed, but no further explanations were given to why a mixed group could gave bigger feet. In contrast, more recent studies suggest that the discrepancies among populations can be explained by diet, footwear use, muscular strength and genetics (Kusumoto, 1990; Kusumoto *et al*., 1996; Ashizawa *et al*., 1997). As said before, an association has been found between the use of footwear in early childhood and flat foot (Sachithanandam and Joseph, 1995).

There are also inconsistencies in the literature with regard to definitions and nomenclatures for foot measurements. Kouchi (1995) defined dorsum height as the height of the dorsum at 54% of foot length, whereas Williams and McClay (2000) and Chuckpaiwong *et al.* (2009) defined it as 50%. On the other hand, Hawes and Sovak (1994) measured dorsum height to the superior surface of the head of the talus. Further inconsistencies can be found in the measurement of the foot from the pternion to the most medially prominent point on the first metatarsal head has been referred as truncated foot length (Williams and McClay, 2000), whilst others refer to it as foot length (Wen *et al*., 1997), ball of foot length (Mauch *et al*., 2008; McPoil *et al*., 2009), arch length (Saltzman *et al*., 1995; Goonetilleke *et al*., 2009) or even first metatarsal length (Sandrey *et al*., 1996). In addition, the equipment and methodology used for measuring the foot do not appear to be standardised and the different approaches (e.g. scanner, photographs, manual) make comparisons of data difficult.

In conclusion, it is imperative to consider the 3-D shape of the foot to provide footwear with good fit and one must bear in mind that there are significant differences in foot measurements among population groups. In this sense, it would be ideal to create a national anthropometry database for every country as proposed by Agic *et al.* (2006) for the Croatian population. Furthermore, ideally, the definitions and nomenclatures of measurements should be standardised.

2.4.1. Variations in foot dimensions

When measuring or capturing the shape of the foot it is necessary to remember that the data often captured refers to a static representation, but the foot is a mobile (dynamic) structure which changes according to the amount of weight borne. The foot contact area (length and width) increases as more weight is applied on the foot, whereas arch height and arch angle decrease significantly between static weight bearing and weight bearing during walking (Hamill *et al*., 1989; Tsung *et al*., 2003). Tsung *et al.* (2003) reported that the subsequent decrease in arch height is strongly associated with an increase in foot length ($r > 0.75$). Thus, the amount of weight bearing has been considered as indicative of arch mobility (Nigg *et al*., 1998). In standing, Rys and Konz (1994) reported that most of the foot expansion (swelling) during standing takes place in the midfoot, lowering the arches and increasing the width of the foot.

Acknowledging such changes in foot shape under different circumstances (e.g. weight bearing, dynamical, non-weight bearing) is crucial for the design footwear to improve fit as well as being comfortable and functional. Therefore, optimum fit is a compromise for a shoe, as it must be in accordance with the following conditions (Rossi, 1988):

- the foot at rest;
- the foot on weight bearing;
- the foot in gait;
- foot at the end of the day;
- foot increases/decreases in shape due to alterations in blood flow or thermal conditions.

Therefore, in order to specify footwear with a good fit, it is imperative to understand the characteristics, dimensions and properties of the foot. Anthropometric measurements are important for this understanding in order to reproduce the three-dimensional shape of the foot and to help classify the foot according to its morphology (e.g. high arched, flatfoot and normal).

2.4.2. *Three dimensional representation of the foot*

The methods most reported in the literature to measure/capture the foot for footwear design include: plaster/foam technique (Mochimaru *et al*., 2000), three-dimensional digitising device (e.g. scanner) (Liu *et al*., 1999; Sacco *et al*., 2003; Cheung and Zhang, 2006), photographic (Freedman *et al*., 1946) and manual measurements (Parham *et al*., 1992; Hawes and Sovak, 1994), with the latter being historically the most common. Methods of capturing the foot using a scanner will be discussed in Chapter 3 and manual measurements are now discussed.

One of the first comprehensive studies reported using anthropometric measurements to reproduce the human foot was conducted by the Armored Research Medical Laboratory in Fort Knox, Kentucky in 1946. They recruited 6278 white and 1281 black US Army inductees and 27 dimensional characteristics were assessed, including heights, girths, lengths and widths (Appendix 2.1) (Freedman *et al*., 1946). Parham *et al.* (1992) presented another US Army report that analysed the data of 293 male and 574 female soldiers. In this study, 26 measurements of the right foot were collected, among other measures (Appendix 2.2). These two Army studies helped the US to design boots that would fit the soldiers properly. Baba (1975) recruited 1844 individuals but the details regarding the measurements taken are not fully reported. In another study, Dahlberg and Lander (1948) measured the feet of 8232 Swedish individuals from 17 to 47 years old with the aim of providing data for the shoe industry. Although 18 measurements were taken, foot height values were not obtained and the procedures for foot measurements were not described in detail. These reports are very old, thus it is likely that these data are no longer representative as better nutrition, different footwear use and muscle strengths will have led to changes in foot shape. In addition, these studies are likely to have recruited healthy and relatively young individuals that serve the army, whereas the foot becomes flatter and broader with age (Dahlberg and Lander, 1948). Finally, as mentioned previously, studies that recruit only nationals from one country may only be representative for that country alone.

Another comprehensive and more recent study was undertaken by Hawes and Sovak (1994). They utilised a sample of 1197 Caucasian North American civilians subjects and took a total of 22 measurements (Table 2.3) in a time span of a approximately 5 minutes. They reported a minimum intraobserver correlation coefficient of 0.81. The purpose of that study was to serve as a reference for shoe manufacturers to construct more accurate shoe lasts for the population. However, although this study presented some valuable data, only male civilians were recruited.

Table 2.3. Measurements used by Hawes and Sovak (1994) to describe three-dimensional shape of the foot.

Dimension	Measure	Procedure	
Foot height	Hallux height	Measured to the superior surface of the hallux.	a
	MPJ height	Measured to the superior point of the first joint.	b
	Dorsum height	Measured to the superior surface of the head of the talus.	c
	Sphyrion fibulae height	Measured at the intersection of a vertical plane passing through the dorsum height on the margin of the medial plantar curvature.	o
	Pternion height	Measured at the intersection of a vertical plane passing through the dorsum height on the margin of the medial plantar curvature.	p
	maximum arch height	Measured at the intersection of a vertical plane passing through the dorsum height on the margin of the medial plantar curvature.	f
Foot length	First digit length	Measured from the most prominent point of the first digit to the most posterior projecting point on the heel.	g
	Second digit length	Measured from the most prominent point of the second digit to the most posterior projecting point on the heel.	h
	Third digit length	Measured from the most prominent point of the third digit to the most posterior projecting point on the heel.	i
	Fourth digit length	Measured from the most prominent point of the fourth digit to the most posterior projecting point on the heel.	j
	Fifth digit length	Measured from the most prominent point of the fifth digit to the most posterior projecting point on the heel.	k
	Fibulare	Measured from the fibulare to the most posterior projecting point on the heel.	l
	Metatarsale tibiale	Measured from the metatarsale tibiale to the most posterior projecting point on the heel.	m
	Akropodion	Length from the head of talus (dorsum) to the akropodion.	d
	Distal heel	Length from the head of talus (dorsum) to the distal heel contact with the surface.	e
Foot breath	Foot breath	Measured between the metatarsale tibiale and fibulare.	n
	Pternion heel breath	Measured with compression to the bony surface at the point of maximum width of the calcaneus at the level of the pternion.	q
	Maximum heel breath	Measured with compression to the bony surface at the point of maximum hell width, 2-3 mm above the standing surface, and approximately 3 cm anterior to the pternion.	r
Foot girth	MPJ girth	Measured encompassing the metatarsale tibiale and fibulare.	s
	Minimal arch girth	Measured with subject elevating the heel and the minimum circumference will be found by serial measurements through the arch.	t
	Mid-arch girth	Measured in the frontal plane passing through the dorsum.	u
	Heel girth	Measured encompassing the dorsum and the point of distal heel contact on the standing surface.	v

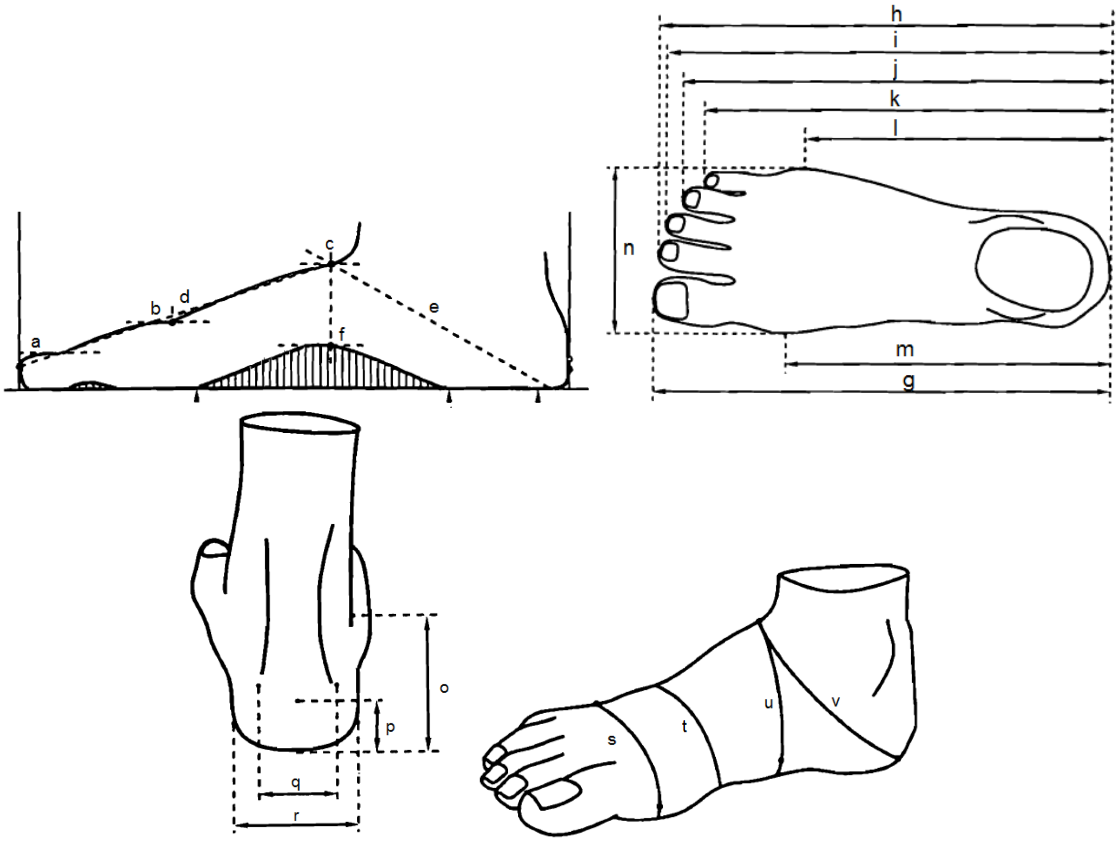


Figure 2.7. Anthropometric measurements of the foot as described in Table 2.3 (adapted from Hawes and Sovak, 1994).

Most of the research involving anthropometry of the foot are limited to length and width data, and are therefore of limited value for representing and modelling the shape of the foot. Although most of the academic researches mentioned in the previous paragraphs regarding the suite of manual measurements needed to describe the three-dimensional shape of the foot were carried out to serve as reference for boot or shoe manufacturers, the literature is very scarce in this field if compared to the size of the footwear market, number of brands and population groups in question, leaving an intriguing impression that commercial shoe manufacturers take such measurements but do not publish them in the scientific literature.

With regard to the equipment used to collect such measurements, the most cited ones are: tape measures (especially for girth values), anthropometers, callipers, rulers and the Brannock. The Brannock is a piece of equipment for the measurement of foot length, foot length at the 1st MPJ and arch length in a reduced time (Janisse, 1992). Regardless of the instruments used, it is important to ensure good maintenance and proper calibration.

It is possible to conclude that the literature is still short with regards to foot anthropometry, especially given that significant differences are found between populations. Most of the reports available are relatively old. Chapter 3 will approach the current methodologies and recommendations for taking anthropometric measurements of the foot in detail.

2.4.3. Foot type classification

As the human foot is a structure with 26 bones and complex joints that varies in morphology and in function, attempts have been made to classify the foot based on the speculation that the structure and mobility can indicate potential development of injuries and preferences in terms of comfort (as exposed in Section 2.2.1). Systematic reviews of the literature performed by Razeghi and Batt (2002) and Redmond *et al.* (2006) indicated that there are multiple methods of foot classification: based on indirect (which includes visual non-quantitative inspection and footprint evaluations) and direct assessments (which involve radiographic techniques and manual measurements). According to Chuckpaiwong *et al.* (2009), between all the techniques that classify foot type, clinical assessment (manual and visual) is considered the most important tool for 69.9% of the specialists, followed by radiography (17.85%) and footprint assessments (11.6%).

Foot type classification can be divided into static (body resting) and dynamic (in motion) (Donatelli, 1996). This is imperative, because although static measurements (e.g. footprints) of the foot are reliable, they cannot predict actual dynamic lower limb function (Hamill *et al*., 1989; Cavanagh *et al*., 1997; Razeghi and Batt, 2002). Cashmere *et al.* (1999) reported that arch height is not predictive of the dynamic behaviour of the foot. Arch height decreases slightly at 4% to 10% of the stance phase of gait, followed by a sharp increase at 10% to 15%. From this point up to 85% of the stance phase, there is a gradual decrease in arch height, but it then tends to increase again from around 85% of the stance phase to toe off (Figure 2.6) (Cashmere *et al*., 1999). On average, the arch will collapse up to 85% during ground contact. However, dynamic assessments are reported as subjective and hard to record objectively (Chuckpaiwong *et al*., 2009).

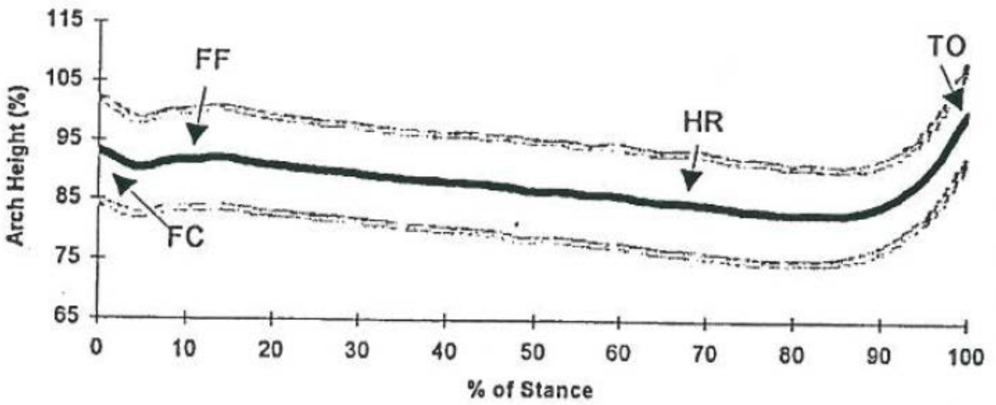


Figure 2.8. Ensemble averages (n = 19) of height of MLA during stance phase of gait. Outer lines indicate one standard deviation on either side of the mean. FC (foot contact) is at 0% of stance phase, FF (foot flat) at 10.5%, HR (heel rise) at 69% of stance phase, and TO (toe-off) at 100% of stance (from Cashmere *et al*., 1999).

Although there are other methods for foot type classification (e.g. rearfoot angle and forefoot abduction angle (Chuckpaiwong *et al*., 2009)), the most common is to classify the foot according to the height of the arch (Nawoczenski *et al*., 1998; Chuckpaiwong *et al*., 2009).

Between the existing ways for foot type classification, the manual measurements rely mainly on the bony eminences that represent important structures of the arch. However, due the bones and soft tissues of the foot, the accurate identification and palpation of the structures of the arch is often difficult. This has lead to concerns regarding the reliability and validity of the manual method (Saltzman *et al*., 1995; Nawoczenski *et al*., 1998). As with other methods, there is a lack of consensus among specialists with regard to procedures (e.g. foot position), equipment and even on nomenclature. For instance, Wen *et al.* (1997) utilised the term ‘arch index’ and, using the same procedure, Cowan *et al.* (1993) used the term ‘bony arch index’. Another good example is what Butler *et al.* (2006) classified as ‘arch height index’ (AHI), and Williams III *et al.* (2001a and 2001b) employed the term ‘arch ratio’ (AR) even though both studies used the protocol described by Williams and McClay (2000). The procedures reported by Williams and McClay (2000) to classify the arch are well established in the literature as having excellent intratester reliability (ICC > 0.939), intertester reliability (ICC > 0.811) and validity (ICC > 0.844). Using their technique, a normal arched foot is considered to have an arch ratio (defined as the height of the dorsum of the foot from the floor divided by the individual's foot length) of between 0.275 and 0.356 (Williams III *et al.,* 2001a and 2001b). If the values are below or above, they are considered as low or high arched, respectively.

The most frequently cited methods of foot type classification are described in Table 2.4. A good number of studies measure the arch only by the absolute value of one point (e.g. height of the dorsum or navicular), rather than scaled to foot length. Williams and McClay (2000) reported that dividing the arch height by foot length is important because, for example, a 5-cm arch height on a size 12 foot would have a very different structure than the same measurement on a size 6 foot.

Table 2.4. Most common measurements and calculations for foot classification using clinical approach.

Classification	Procedure
Arch height	Distance between the navicular tuberosity to the supporting surface (Razeghi and Batt, 2002).
Arch height index / arch ratio	The height of the dorsum of the foot from the floor at 50% of the foot length divided by the individual's truncated foot length (Williams and McClay, 2000).
Arch stiffness	Calculated as the relative arch deformation (see description below).
Arch index	Arch index was calculated as the ratio of the navicular height to the truncated foot length (Wen *et al*., 1997; Williams and McClay, 2000).
Angle of first ray	Measured between the floor and the long axis of the first metatarsal (Williams and McClay, 2000).

Arch stiffness is speculated to determine the level of injury risk that an individual is exposed to. Arch stiffness (or mobility) is defined as the relative arch deformation (RAD), calculated as described by Nigg *et al.* (1998):

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

where AHU is the measurement of the arch height taken in an unloaded (i.e. 10% of weight bearing) position and AH is the arch height measurement taken in a full (i.e. 90% of weight bearing) weight bearing position. In a study which recruited 12 males, Nigg *et al.* (1998) found a positive correlation between RAD and tibial rotation: when using orthoses, tibial rotation tends to be reduced systematically on people with a flexible foot whereas on a stiffer footed individual it increases. As such, rigid arches are poor shock absorbers. According to Zifchock *et al.* (2006) there are no differences between genders for arch height index (AHI), but women do tend to have less arch stiffness than men which makes them more prone to developing soft tissue injuries. In addition, there is no relationship between age and AHI or arch stiffness, but the dominant foot tends to have a higher AHI than the non-dominant foot (Zifchock *et al*., 2006). They explain this is due to the fact that the non-dominant foot balances the body, thus experiences more loading, causing the ligaments of this foot to become more elongated, resulting in a higher AHI.

2.5. Footwear comfort

Comfort is an extremely important factor when designing footwear (Goonetilleke and Luximon, 2001; Mundermann *et al*., 2001) and is generally related to the absence of pain and discomfort. According to Head *et al.* (2010), it is often the main aspect considered when purchasing footwear, together with footwear support. Comfort also allows runners to maintain aerobic work for long periods of time (discomfort precedes pain). However, the perception of comfort relies on sensorial information received and on the shape of the foot, both of which are dependent on intersubject variability, related to psychological and neuro-physiological attributes (Nigg *et al*., 1999; Clinghan *et al*., 2007). Pain tolerance depends on each individual's ability to interpret pain stimulus and anxiety levels (Pen and Fisher, 1994). Thus, as comfort is influenced by an individual's foot characteristics, there is no comfortable shoe for everyone (Miller *et al*., 2000).

Recent studies have indicated a link between body alignment, plantar pressure, shoe fit and self-perceived comfort (Jordan *et al*., 1997; Clinghan *et al*., 2007). Hence, important factors for the individual judgement of comfort that should be considered are (Cavanagh, 1980; Chen *et al*., 1994):

1. fit;
2. alignment of the lower extremity;
3. minimization of perspiration;
4. good thermal insulation;
5. sole flexibility;
6. upper flexibility.

Also, according to Mundermann *et al.* (2001), comfort can be related to injury risk and performance. Comfort increases with a greater range of tibial rotation which decreases the eversion angle and gives a higher maximum plantarflexion (Miller *et al*., 2000; Mundermann *et al*., 2003b). Also, differences in comfort can be partially explained by differences in kinematic and kinetics variables and muscle activity of the lower limbs (Mundermann *et al*., 2003b), indicating that comfort can be a good predictor of performance, but evidence for this is still limited in the literature.

2.6. Summary

Reviewing the literature, it is possible to conclude that the way shoes are being manufactured currently is far behind what would be the ideal product. The main gaps in the literature are.

- No standard procedure for the prescription or manufacture of foot orthoses has been found.
- Perfect fit is hardly ever achieved when only length and width measurements are available for footwear.
- The vast majority of running shoes divide individuals into two broad categories: those that need cushioning and those that need support (pronation control). However, users with certain types of feet might prefer insoles with different characteristics (hard, textured and so on) in terms of comfort and may require different properties for minimising the risks of injury and improving performance.
- Most of the research is concentrated on special individuals (i.e. athletes or people with gait/foot problems) rather than healthy asymptomatic runners. However, to deliver personalised footwear to the high street, the 'normal' runners must be considered.

Therefore, there is no comfortable shoe for everyone, so some might be comfortable for a group of runners and but not for another (Chen *et al*., 1994). As Nigg *el al.* (1998) reported, people respond differently to inserts and that an optimal insert may depend on specific anatomy, morphology, functional behaviour and sensitivity of each individual to external signals. For instance, Miller *et al.* (2000) stated that one of their shoes were more comfortable for individuals with high halluxes and wide forefeet. This gap between the currently available shoes and the optimal footwear would only be possible to be fulfilled with the personalisation process. In this case, only the personalised footwear could allow the inside of the foot as a contoured sole, something that manufactures do not make today because it is time consuming and thus would make the shoes more expensive (Cavanagh, 1980).

Finally, it is not known how best to measure feet in this context nor even whether the design of a personalised running shoe can positively (or not) affect comfort, performance, and the lower extremity biomechanical variables in comparison to the generic shoes currently available on the market. Therefore, the next chapter will identify the process required to specify personalised insoles using additive manufacturing and the most common ways of footwear evaluation in terms of comfort, performance and biomechanics.

Chapter 3: Literature review: research methods

3.1. Introduction

In the previous chapter, the published literature confirmed the idea that footwear ideally needs to be personalised to provide optimal properties in terms of comfort, performance, support and injury prevention. The main findings can be summarised.

- Fit is one of the main properties of the shoe. It is linked to comfort, injury and damage prevention.
- Measurements such as the height of the medial longitudinal arch can indicate the potential development of overuse injuries.
- In the construction of footwear, a good understanding of the 3-D shape of the foot is essential to allow optimum fit, and to provide individual requirements and preferences in terms of comfort and support.
- The running shoes available currently on the market are still far from what can be considered ideal. This gap could be fulfilled by their personalisation.

The next step is to discuss additive manufacturing (AM) and the process required to personalise footwear. In addition, it is important to investigate ways of evaluating footwear in terms of comfort, performance and lower extremity biomechanical variables.

This chapter will examine the methods and materials that may be potentially used to specify and evaluate personalised footwear. The objectives are to:

- synthesise the current knowledge about scanning, anthropometric measurements, reverse engineering and AM for specifying personalised products;
- describe and critically discuss some of the commonly used methods for evaluating footwear in terms of comfort, performance and biomechanical variables;
- critique the advantages and disadvantages of the methods used for specifying and evaluating footwear in the context of this thesis.

3.2. *The personalisation process*

In order to develop a possible process for the design and manufacture of personalised footwear using reverse engineering and AM, two potential elements were identified and are critically discussed in this section:

1) Foot capture:
   - 3-D scanning;
   - anthropometric measurements.
2) Additive manufacturing technology:
   - insole design;
   - specialist design.

3.2.1. Foot capture

Capturing the foot is essential to ensure the footwear will representative of the individual's characteristics. Chapter 2 reported the most common methods to capture the foot, which include: plaster casting, foam impression and photographing. Among these, scanning and manual techniques are believed to be the most appropriate in this context and will be discussed in this section.

3.2.1.1. 3-D scanning

Three-dimensional scanners are devices used to capture and digitise an object and can be used for a wide range of applications, from the entertainment industry to the health sector. They started to gain popularity at the end of the last century with rapid advancements in scanning technology.

Although the application of scanners for foot capture has been widely reported in the literature, the use of scanner techniques in anthropometry is recent. In a review of the literature, Telfer and Woodburn (2010) documented the potential applications for 3-D scanners in the commercial, clinical and research fields in relation to the human foot. These include: fabrication of orthotics, measuring the surface area of the body and taking anthropometric measurements. Also according to Telfer and Woodburn (2010), some benefits of 3-D scanning in comparison to traditional techniques are:

- it allows a large number of individuals to be scanned quickly and easily (and cleanly);
- the data can be analysed in a convenient way for the researcher;
- it maximises time and cost savings;
- reduces the material waste, like plaster and foam;

- by avoiding the need for data transportation, the cost of generating a representation of the plantar surface of the foot using a scanner is estimated to be around 10% of that using plaster cast.

There are two most commonly reported types of 3-D scanners in the literature for foot capture: light and laser. The laser scanner as a general rule emits a line of laser light on the surface of the object, which is captured by a camera (or cameras). Data are then presented as 3-D points in space in discrete sections, referenced by their XYZ coordinate values (Zhang and Molenbroek, 2004; ISO 20685, 2005; Yahara *et al*., 2005). It is important to know the spacing of these sections because as Zhao *et al.* (2008) found in a study to obtain foot girths using a scanner to customise footwear, the bigger the spacing, the less accurate the results. The collection of points in these sections is referred to as “point cloud data” and the resolution refers to the distance between these points. As point clouds themselves are of little use, the data is generally converted into 3-D surfaces through a method called ‘polygonisation’ (Bibb, 2006), which determines polygon facets (in most cases, these are triangles) by using the intersection of the points on the required plane, as described by Zhao *et al.* (2008). One must bear in mind that triangulation errors can occur due to the quality of the laser beam (Witana *et al*., 2006), and that triangulation only provides an approximation of the surface. The phases from point cloud data to a triangulated surface are shown in Figure 3.1.

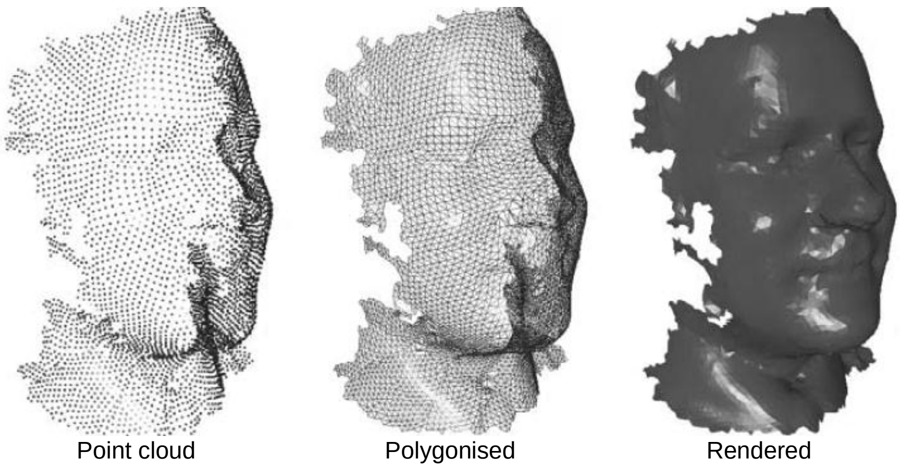


Figure 3.1. A triangular polygon mesh created from a point cloud (from Bibb, 2006).

Scanners can be used for multiple purposes and, when scanning the human foot in particular, the most common sources of inaccuracy are:

- the scanner data does not separate the toes, which influences the foot length and width values (Xiong *et al*., 2008);
- foot girths values are difficult to obtain because they are not linear like length and width measurements (Xiong *et al*., 2008);
- the scanner beam can be diverged due to dust or high levels of ambient light (Witana *et al*., 2006);
- depending on the type of scanner, the point cloud construction methodology can affect some measurements. An example is heel width where, according to Witana *et al.* (2006), in the rearfoot region, the lower leg is also captured;
- resolution, colour perception, luminance and shadowing of body parts can influence the final data (ISO 20685, 2005).

Foot scanners vary according to the resolution of the scan, number of cameras and time needed to do a scan. Generally speaking, the accuracy of laser scanners has been reported as being from 0.5 – 2.0 mm (Yahara *et al*., 2005; Houston *et al*., 2006; Goonetilleke *et al*., 2009). The ISO 20685 (2005) suggests that before the scan itself, the device should be tested with an object of known dimensions. The maximum tolerable error reported in the literature also varies. For example, the ISO 20685 (2005) reported a maximum tolerable error of 2 mm for foot dimensions, whereas Zhao *et al.* (2008) suggested that inaccuracies of around 5 mm can be tolerated for footwear manufacture. These studies do not provide a clear rationale for stipulating these maximum acceptable errors, which could be based on user experience with the product (e.g. fit and comfort properties) or purely on the manufacturing process (e.g. precision when assembling different parts of the shoe).

Attempts have been made to use the scanner to facilitate the production of personalised footwear for the high street by using foot data to build fully customised shoe lasts (Sacco *et al*., 2003; Leng and Du, 2005; Witana *et al*., 2006). However, this is still a costly process for personalised shoes, since each last is expensive to produce and would be needed for every customer. A cheaper solution proposed in the literature for customised footwear is to select a 'last of best fit' for an individual, based on the anthropometric measurements from a digital library of pre-existing shoe lasts (Luximon *et al*., 2003). This alternative nevertheless cannot be considered as fully personalised. Scanners are also used for the production of accommodative foot orthoses. Laughton *et al.* (2002) in a study which compared the reliability and accuracy of plaster casting, foam impressions and laser scanning to fabricate orthotics, reported that the laser scanning is reliable and appropriate for such application, although the production of orthotics in this way has not been fully researched.

In summary, the use of 3-D scanners for foot capture is becoming more popular and they offer advantages in comparison to the traditional methods. However, it is important to check the scanner's characteristics, like accuracy and resolution as these will determine the quality of the data. It is also fundamental to explore the scanner as part of the personalisation process: time required, foot position, reliability and compatibility of the data, and the hardware and software involved.

Foot position

As mentioned in Chapter 2, the foot is a structure that changes in dimensions under different loading conditions, so its position must be considered when defining methodologies for foot capture. Although it appears to be a consensus that the foot is a dynamic structure, the literature is contradictory with respect to the ideal amount of weight bearing needed when capturing its shape. The majority of studies have used a semi-weight bearing position, whereby body weight is evenly distributed between both feet (for example: Freedman *et al*., 1946; Parham *et al*., 1992; Luximon *et al*., 2001). Others have measured or captured the foot with full-weight bearing on one foot (Hawes and Sovak, 1994; Cavanagh *et al*., 1997; Liu *et al*., 1999), non-weight bearing (Goonetilleke *et al*., 1997; Olivato *et al*., 2008; Chuckpaiwong *et al*., 2009) or even a combination of full and non-weight bearing (Williams III *et al*., 2001b). Unfortunately, most of these studies do not provide clear explanations for their choices. The actual benefits of a given foot position in terms of improving comfort and support are also not well discussed in the literature. Even research conducted for military boot design (Freedman *et al*., 1946; Parham *et al*., 1992) or for shoe manufacturers (Dahlberg and Lander, 1948; Hawes and Sovak, 1994) do not explain why the foot was captured adopting a particular position. One of the few arguments for measuring the feet unloaded is to obtain a 'pure' foot shape (Olivato *et al*., 2008). According to Houston *et al.* (2006) when the foot takes 25% of the body weight, 71% of the changes in shape that occur with full of weight bearing are observed. They indicated that loading the foot with 10-50% of body weight generally showed good results for casting and suggest that most of the changes to the foot shape occur with 10% of weight bearing.

The most documented research on foot capture positions has been undertaken by researchers involved in the production of orthotics. For orthotic construction, optimal positions of foot capture have been explored, including: semi-weight bearing, semi-weight bearing with the subtalar joint in its neutral position, supine non-weight bearing, prone non-weight bearing and sitting semi-weight-bearing (McPoil *et al*., 1989; Guldemond *et al*., 2006). The majority of the research suggests that an impression of the foot should be taken when it is in a subtalar neutral position, when the foot is neither pronated nor supinated, similar to that which occurs during the mid-stance phase of gait (McPoil *et al*., 1989; Laughton *et al*., 2002), when the mid-tarsal joint becomes fully locked (McPoil *et al*., 1989). However, there is no consensus regarding the actual subtalar neutral position and its assessment has been questioned (Miller and McGuire, 2000). Table 3.1 summarises the literature and it can be seen that a clear rationale for adopting a particular posture is not often reported.

Table 3.1. Descriptive summary of the literature on foot capture to produce orthotics or insoles.

Authors	Position adopted	Position rationale	Application	Technique
Mundermann *et al.* (2003b)	Foot in a subtalar neutral position (n = 21)	Based on Losito (1996)	Moulded and posted orthotics	Plaster casting
Davis *et al.* (2008)	Neutral non-weight bearing supine (n = 19)	Not provided	Orthotics	Plaster casting
MacLean *et al.* (2008)	Not provided (n = 12)	Not provided	Orthotics	Suspension casting
Sun *et al.* (2009)	Non-weight bearing (n = 50)	Not provided	Three-quarter shoe insoles	3-D scanner
Pallari *et al.* (2010)	Weight and non-weight bearing. Podiatrist decided which position is suitable (n = 7).	Not provided	Orthotics	3-D scanner

Laughton *et al.* (2002) reported that laser scanning together with foam box impressions tend to produce bigger rearfoot width measures than the casting method. This is likely to be due to shrinkage of the plaster when drying, compressing the soft tissue of the foot. As mentioned in the previous section, these researchers compared the reliability and accuracy of different techniques (laser scanning, plaster casting and foam box impression) to capture the foot to fabricate orthotics. They concluded that foam impressions resulted in greater rearfoot and forefoot width values than the other two techniques – maybe because of the outward expansion of the soft tissue of the foot as it is pressed into the box. These findings are supported by Guldemond *et al.* (2006), who reported that foam box methods resulted in larger contact areas and better rated walking convenience than plaster methods. Although no definition was given to ‘walking convenience’, the one was assessed using a 10-point scale. Furthermore, Laughton *et al.* (2002) found that the scanner technique required the individual to be seated with the hips, knees and ankles maintained at 90° to produce an accommodative orthosis with the subtalar joint in its neutral position. On the other hand, Sun *et al.* (2009) scanned the foot non-weight bearing, using a special foot support so that the plantar shape was captured in what they defined as 'natural state of total relaxation'.

However, ideally, to design personalised footwear foot scan data should represent the dynamic movement of the foot, for the reasons explained in Chapter 2. Such scanners that capture a maximum of 46 frames per second (Schmeltzpfenning *et al*., 2010) are becoming more available, enabling the generation of point cloud data for the different phases of ground contact and the design of footwear combining multiple frames. However, these systems are still expensive and exclusive and their application to footwear design remains unknown.

In summary, when capturing the foot, significant changes in shape must be considered. The majority of work investigating the differences in foot dimensions has been done by orthotic developers, while research on footwear design rarely provides a rationale for foot posture. Ideally, foot data should represent the changes of its structure while in motion. If this is not possible, static foot capture is often used instead, but there is no consensus in the literature with regard to the optimal position of the foot.

3.2.1.2. Anthropometric measurements

As exposed in Chapter 2, a good understanding of the 3-D shape of the foot is essential to provide footwear with good fit and to specify its optimal properties for a given individual. For instance, the measurement of foot length from the most prominent point in the heel to the 1st and 5th metatarsophalangeal joints (MPJs) can help to indicate where the shoe needs to flex. The use of a scanner to facilitate taking such measurements is becoming more popular, although the manual technique is still widely used. Table 3.2 summarises the main characteristics, advantages and disadvantages of both techniques. According to Payne (2007), it takes around 2 minutes to prepare and scan the foot, but this study did not include the time taken to identify and mark the anatomical landmarks, which are required to extract anthropometric measurements. Also, the most time consuming part of obtaining foot dimensions from the scan data is working with the software to create planes. Obtaining the measurements can therefore take longer than the actual manual work, although individuals do not need to be present during this phase. Witana *et al.* (2006) reported that there were no significant differences in terms of the measurement when comparing manual and those taken automatically using a scanner.

Table 3.2. Main advantages and disadvantages of scanning and manual techniques for measuring the foot.

	Scanning	Manual
Stage(s)	(1) foot scanning; and (2) extracting measurements via software.	(1) taking anthropometric measurements directly.
Advantages	• It is quick to scan the foot, so individuals are not required to stay for very long on site. • Measurements can be extracted when is more convenient to the researcher as data is digitised. • Measurements can be taken automatically by a software (e.g. Witana *et al*., 2006).	• Measurer can identify bones prominences and anatomical landmarks by palpation. • Methodologies are well established in the literature and, once a strict protocol is followed, the results should have high reliability. • Has only one stage, so time can be optimised.
Disadvantages	• Difficult to identify the anatomical landmarks (e.g. navicular, head of metatarsals) so these must be identified manually by palpation and marked before the scan (Houston *et al*., 2006; Goonetilleke *et al*., 2009). • The extraction of measurements can take longer than the manual technique if not automated in the software. • The scans do not separate the toes, which influences foot length and width values; and foot girths values are difficult to obtain because they are not linear measurements (Xiong *et al*., 2008).	• Time consuming in comparison to scanning, so participants can get fatigued. • Reliability of the measurements depends on the experience of the researcher and calibration of equipment used.

If a 3-D scanner is used to take anthropometric measurements, the recommendations listed in Section 3.2.1.1 also apply here, but if done manually, it is important to consider the following:

- according to Weiner and Lourie (1981) the repeatability of the measurements must be checked if more than one specialist is assigned to do the work;
- the level of experience of the measurer will influence the results (Witana *et al*., 2006), so training or practice sessions are important prior to data collection (Garbalosa *et al*., 1994);
- it is important to standardise the position, orientation of the scales and proper calibration of the instruments (Garbalosa *et al*., 1994; Tsung *et al*., 2003);
- according to Zhao *et al.* (2008), when taking girth measurements, apertures between the tape and the foot surface are likely, because of inconsistencies in the foot's surface;
- it is important not to apply any pressure on the soft tissue when taking measurements (Weiner and Lourie, 1981), as manual measurements can be

approximately 1 mm shorter than photographic approaches due to soft tissue compression (Freedman *et al*., 1946);

- participants can become fatigued, thus changing the shape of the foot due to swelling (Witana *et al*., 2006).

When measuring the foot manually, it would be reasonable to consider the foot margin, characterised by a curvature of the soft tissue and being as much as 1.2 cm above the floor surface. The values for heel breath for example, can increase by approximately 1 cm considering the margin of the foot (Freedman *et al*., 1946). Regardless if measuring manually or with a scanner, the identification of specific anatomical landmarks (by palpation and then marking) helps to provide more accurate measurements (Goonetilleke *et al*., 2009). The most cited anatomical landmarks include: the dorsal arch point, metatarsale tibiale (1st MPJ), metatasale fibulare (5th MPJ), the pternion, sphyrion fibulare, the navicular, and the head of the first and fifth metatarsals (Figure 3.2) (Kouchi, 1995; Chuckpaiwong *et al*., 2009).

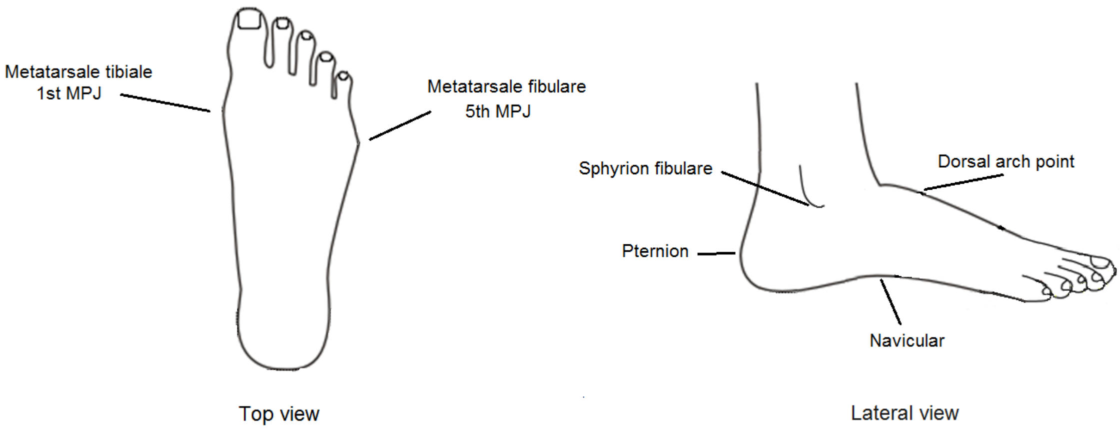


Figure 3.2. Anatomical landmarks cited in the literature.

In the context of the footwear personalisation process, anthropometric measurements can help in the specification and design which is supported by specific examples in the literature. Evidence indicates that 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). Concerning insole design and the measurement of arch height, Mundermann *et al.* (2001) reported that people with a low arch (LA) foot tend to prefer harder insoles, whereas high arched (HA) individuals tend to choose softer ones. Although arch height may be useful for indicating the comfort and support properties, other measurements can also be important in determining individual preferences/needs, including upper height at the midfoot and forefoot, heel width and toe box space (Goonetilleke *et al*., 1997; Witana *et al*., 2004).

In conclusion, anthropometric data can be important for the identification of the best properties and characteristics of the shoe (e.g. insole material, midsole and upper design) for a given individual, but the suite of anthropometric data that needs to be collected for designing personalised footwear is unclear from the literature. These can be taken manually or using a 3-D scanner.

3.2.2. Additive manufacturing technology

Once the foot has been captured, the next element of the process refers to the design and fabrication of the parts. Rapid prototyping is the term for various technologies that have emerged in the last 20 years, targeting the quick fabrication of parts directly from 3-D digital data (Eyers and Dotchev, 2010). Initially, this technology was mostly used to make prototypes for product development but, with its advancement, the term 'additive manufacturing' (AM) started to be used and it refers to those rapid prototyping technologies that are considered as viable for manufacturing finished goods or end-use products. Therefore, AM is the collective term assigned to a group of manufacturing processes which fabricate three-dimensional parts directly from a CAD file through an additive or layer-by-layer approach using either liquid, powdered or sheet material. The direct nature of these processes eliminates tooling to be used as parts of assemblies or as standalone products (Hopkinson and Dickens, 2001; Hague *et al*., 2003a). This is considered a technology of the future because of its capability of creating objects from scratch, including any complex geometry.

There are many AM processes, but the key technologies for producing polymer parts are: fused deposition modelling (FDM), 3-D printing (3DP) and laser sintering (LS). A list of the most popular AM processes and materials is provided in Table 3.3.

Table 3.3. Material types and most popular technologies for AM (from Eyers and Dotchev, 2010).

Material type	AM technology	Manufacturer	Materials
Photopolymer resin	Stereolithography	3D Systems	Variety of epoxy resins and nano-composite resin.
	Envisiontec Perfactory (2D mask)	Envisiontec	Epoxy-acrylic resins, nano-composite resin and acrylic resin (investment casting).
	Polyjet (3D printing)	Object Geometries	Proprietary photopolymers and biocompatible resins.
Plastic	Selective Laser Sintering	3D Systems	Nylon (Polyamide) 12 (DuraForm PA®), GF polyamide, aluminium filled polyamide, composite plastics and CastForm (polystyrene/wax system for investment casting).
	Laser sintering	EOS GmbH	Nylon (Polyamide) 12, GF polyamide, aluminium filled polyamide, flame retardant polyamide, carbon fibre filled polyamide and polystyrene (investment casting).
	Fused Deposition Modelling	Stratasys	ABS, PC-ABS, PC and biocompatible ABS.
	Multi-jet Modelling (3D printing)	3D Systems	Polymer (wax-like).
	Multi-jet Modelling	Solidscape	Polymer (wax-like).
Metal	Direct metal laser sintering	EOS GmbH	Stainless steel GP1 and PH1, cobalt chrome SP1 and SP2, titanium Ti64, Ti64 ELI and Ti CP, maraging steel MS1, AlSi20Mg and EOS Inco718.
	Selective laser melting	MTT	Stainless steel and titanium.
	Laser Cusing	Concept Laser	Stainless steel, hot-work steel, titanium TiAl6V4, aluminium AlSi12, AlSi10Mg and nickel-based alloy (Inconel 718).
	Electron beam melting	Arcam AB	Pure titanium, Ti6Al4V, Ti6Al4V ELI and cobalt chrome.

Among these technologies, laser sintering (LS) is the most appropriate for making end-use products because it can provide/produce strong, durable and functional end-use components. Also, LS requires less post-processing compared to technologies which use support structures. In addition, the lack of support structure maximises geometrical/design freedom. LS creates 3-D solid objects by selectively fusing powder with a CO_2 laser in successive layers (0.1 mm thick), turning the powder material into solid objects (Saleh and Dalgarno, 2010). According to Eyers and Dotchev (2010), the process chain has only one stage: from design to the final product (Figure 3.3).

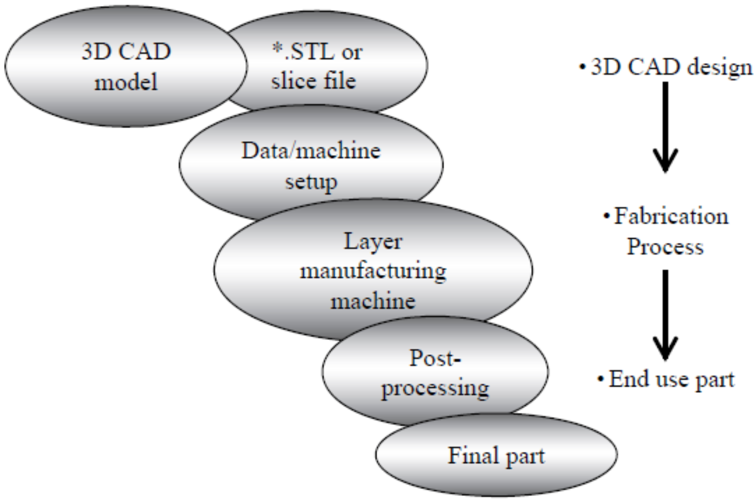


Figure 3.3. AM process chain (from Eyers and Dotchev, 2010).

Successful applications of AM range from cooling ducts for Formula 1 cars to hearing aids (Hague, 2005; Tromans, 2005). According to several authors, AM has potential advantages in comparison to conventional manufacturing methods, such as injection moulding and machining. In the view of footwear personalisation, according to Hopkinson and Dickens (2003) these are.

- AM does not require any tooling as parts are manufactured directly from the CAD file, removing significant costs in footwear development. Manufacturing moulds for component production and lasts for footwear assembly for individual customers/every customer would not be economically feasible using standard techniques.
- AM offers extensive design freedom compared to conventional techniques, such as moulding. This coupled with the potential economic production of single units means that it is feasible to produce fully personalised shoes that offer optimal comfort, performance and injury prevention.
- Footwear sole units can be manufactured entirely as one part, eliminating the need in conventional shoe manufacturing to make parts using different techniques and assembling them.
- AM can potentially produce one-off shoes economically, which cannot be achieved with standard manufacturing techniques, such as moulding, due to the tooling costs.
- AM processes involve minimising waste as parts are built additively. With LS the unsintered powder can also be recycled a number of times.

Despite the advantages, AM is relatively new and it is not possible to manufacture functional sports footwear for the high street at this stage. Limitations include: the high costs associated with the AM machines and their maintenance, and the cost, range and mechanical properties of materials are also still limited (Hopkinson and Dickens, 2003). Hague *et al.* (2003a) suggested this limitation is partly due to the fact that the demand for AM is relatively low, such that the high cost of new material development often cannot be justified. According to Williams *et al.* (2003), the cost to manufacture any object should take into account the volume of material needed, the cost of materials, labour, machine operation, annual maintenance, time to build a part, the number of machines and the number of parts produced per year. As the development of functional footwear using AM is currently not viable and is being investigated by the other research groups in the Elite to High Street project, this thesis will focus on the specification and evaluation of personalised insoles. It is expected that these insoles can be incorporated to the footwear at a later stage.

As AM is not ready yet to deliver footwear to the high street, as an alternative solution Luximon and Luximon (2009) developed software capable of generating customised shoe lasts based on measurements of the feet. Lasts could then be manufactured in around 3 minutes using a special shoe-last computer numerical controlled (CNC) machine. Although this is an innovative concept, no further details were given on the costs and the footwear generated could only offer customised fit, making this process more applicable to the manufacture of social shoes, as the functional requirements or material preferences are not customised.

In conclusion, AM technology advanced from rapid prototyping and has enabled the production of end-use products. The direct nature of this process eliminates tooling and allows geometric freedom, making it promising in the long term development of personalised components, such as for footwear for the high street. This potential is mainly based on the ability to produce personalised footwear at no extra cost, without the need to build lasts and moulds for every consumer. However, the current limitations, which include high costs and the materials available, impose difficulties for the production of functional footwear. Considering the current stage of the technology, this thesis will focus on the specification and evaluation of personalised insoles.

3.2.2.1. Insole design

Before the actual fabrication of parts using AM, the data from the foot capture element must meet individual needs. In the case of personalised components of any kind, often the geometry is captured using a scanner and this data is then manipulated into accurate 3-D digital models, following a process often referred as ‘reverse engineering’. The CAD software that allows reverse engineering is a vital tool for the design of personalised insoles, since the design phase is performed electronically to make the final model compatible with AM – the technology accepts, nearly in all cases, files in the stereolithography (STL) format for manufacture (Gibson *et al*., 2010).

The process of reverse engineering and manufacturing customised components using AM is mainly found in relatively recent literature. For foot orthotic design, Pallari *et al.* (2010) described the main elements as: data filtering (removing spurious material), thickening, wedging and creating metatarsal bars. The design rules they suggest can be considered a starting point for orthotic production, but further refinement is needed to construct personalised insoles. In customised seat manufacturing, the methodology also included data cleaning, together with data smoothing (Tuck *et al*., 2008). Table 3.4 summarises the literature which utilised similar process of scanning, CAD design and manufacture using AM.

Table 3.4. Summary descriptions of papers which utilised similar process to the one proposed in this thesis.

Authors	Component designed	Software used	Rationale for software use	Main actions
Bibb *et al.* (2006)	Denture framework	FreeForm	Mainly because of “its capability in the design of complex, arbitrary but well-defined shapes that are required when designing custom appliances and devices that must fit with human anatomy” (Bibb *et al*., 2006).	Exact actions not provided, but mentioned that they are fully described in Williams *et al*. (2004) and were conducted according to established principles in dental technology.
Tuck *et al.* (2008)	Aircrew seating	Raindrops Geomagic Studio	Not provided	Data cleaning; smoothing; creation of non-uniform rational B-splines surface.
Sun *et al.* (2009)	Personalised insoles	Geomagic Studio and Magics RP	Not provided	Using Geomagic Studio: identification of points in the data to define the shape; elimination of the other elements in plantar shape. Using Magics RP: combination of the three-quarter plantar image models with commercially available shoe models.
Pallari *et al.* (2010)	Customised orthotics	Magics CAD package	Not provided	Filtration of the data (to remove noise); exclusion of spurious material; distally extruding the surface into 5 mm. Further actions were performed to ensure the functional properties of the orthotics.

Regarding insole design, the aim of the reverse engineering process is to rectify and delete unwanted scan data without losing the geometric accuracy. To achieve this, the reverse engineering software should potentially allow the following features:

- deletion of unwanted data – includes the selection of points in the data;
- noise reduction – compensation for scanner error (noise) by moving points to statistically correct locations;
- data smoothing – smoothing of the surface to remove undulations of the foot;
- boundary smoothing – smoothing of jagged edges on the boundary by reconstructing the polygon mesh;
- thickening – to extrude or offset the surface data to produce a finite bound volume.

These features identified still need to be explored in conjunction with the capabilities of the software in use. CAD software that allows the transformation of 3-D scan data into parametric models generally allows this type of data manipulation. According to Bibb (2006), to be used successfully in AM, the STL files should not contain gaps between facets (triangles, in this case) and these facets should identify which is the inside and outside surface.

In conclusion, insole design using reverse engineering is essential because the final data needs to be converted into an STL file to be compatible with the AM technology. Although the recent literature has provided recommendations in product design using CAD software for specific applications, the exact actions and software for insole design are still unclear.

3.2.2.2. Specialist design

Finally, the concept of personalised footwear suggests that all characteristics of the shoe, such as fit, comfort, support and performance are unique. Fit and comfort can be defined from foot capture and anthropometric measurements. Optimal performance, support and/or 'correction' of the lower extremities can be achieved by an examination of the lower limbs. This examination ideally should be conducted by a physiotherapist, podiatrist or other specialist and may indicate static as well as dynamic assessments, for example the evaluation of pathologies by palpation or performing gait analysis. Pallari *et al.* (2010) reported on the production of orthoses for individuals with rheumatoid arthritis following a process of capturing foot geometry using a scanner.

Data were manipulated by a CAD professional with input from a podiatrist, indicating that the idea of specialist personalisation is feasible. However, further studies are needed to investigate what examinations are required and how the interactions between the podiatrist and designer would work. In this regard, the A-Footprint research project, which is a collaboration of 12 partners across 7 European Union member states, is investigating ways to automate processes to speed up the manufacture delivery and supply of personalised orthotics though digital scanning, CAD and AM (A-Footprint, 2011). This 4-year project, that started in 2009 and ends in 2013, is expected to contribute to the development of orthotics that, not only meet the fit and comfort, but also the biomechanical requirements of the individual.

Biomechanical evaluation of the lower extremities may also involve assessment of the optimal properties for enhancing the performance of a particular individual. For example, recent studies suggest that the longitudinal bending stiffness at the MPJs of sprint shoes can improve performance (i.e. decrease sprint time and increase net power), but optimal stiffness may depend on specific individual force producing capabilities (Stefanyshyn and Fusco, 2004; Toon, 2008).

If an examination of the individual reveals that extra features are needed, these must be included in the design phase reported in Section 3.2.2.1. Similar features are described by Pallari *et al.* (2010), such as rearfoot wedges, metatarsal pads, bars, cut-outs and so on. This part of the personalisation process is complex (and expensive) as a specialist is required to advise on foot or gait abnormalities. Further exploration particularly regarding the interaction between the podiatrist and the CAD designer is needed.

3.3. Footwear evaluation

Once the personalisation process has been established, ways of evaluating the footwear need to be determined. As mentioned in Section 2.3 (Chapter 2), the aim of the ideal running shoe is to provide comfort, support and improve performance. Therefore, the following sections will approach the most common methods reported in the scientific literature to evaluate these variables. These methods will be introduced, discussed and the advantages and disadvantages in the context of this thesis will be exposed.

3.3.1. Comfort

As reported in Chapter 2, comfort is the most important component of footwear. It will dictate if a customer buys the shoe in the first place and will allow the sport/activity to be performed for extended periods. Comfort is a condition of physical and mental harmony with the environment and is related to the psychological and neuro-physiological attributes of an individual, thus dependant on intra-subject preferences. According to Helander and Zhang (1997), comfort and discomfort are two different factors that can be quantified independently. They have reported, from a series of studies with chair users, that discomfort is affected by biomechanical factors and fatigue, whereas comfort is affected by the aesthetics of the chair design and sense of well-being. A product in itself cannot be comfortable: it becomes comfortable during its use and the user decides whether it is comfortable or not, by using the product, based on his/her own experiences (Vink et al., 2005). In footwear, comfort does not mean cushioning (although the two can be related), as cushioning is simply the amount of cushion and some people may prefer harder shoe properties. In a review of the literature, Nigg *et al.* (1999) reported that comfort is also related to muscle activity as optimal insole/footwear design reduces muscle activity, hence is comfortable because the resulting fatigue is minimised.

With regard to comfort assessment, Mundermann *et al.* (2001 and 2002) suggested that when evaluating insole comfort, a control (placebo) condition should be used in the experimental design. They explained that self-perceived comfort is rated based on previous experiences and adding a control condition means that there is a common base of comparison which can be used as a standard for further assessments. For instance, if a soft material is rated after a hard shoe, then it will feel softer than if it is tested after a softer material. Based on these findings, they made recommendations for assessing footwear comfort using multiple experimental conditions: have a control condition before each assessment; determine repeatability; and have four to six sessions for long term comfort testing.

In the literature, there are several ways for assessing comfort, three of which are most often used for insoles and footwear: continuous scales (e.g. visual analog scale, VAS) that can be either a 0-100 mm or 0-150 mm scale (Mundermann *et al*., 2001; Mundermann *et al*., 2004), ordinal scales (e.g. Likert) and raking scales (Mills *et al*., 2010), which asks the individual to rank the shoes/inserts in order of the most to the least comfortable. Table 3.5 summarises the most common ways and list the main advantages and disadvantages of the techniques. The Likert scale is usually 5 to 13-point and captures the intensity of a sensation. In a study with 20 subjects, Mills *et al.* (2010) compared the VAS, Likert and ranking scale to determine the most reliable to determine shoe comfort. They concluded that the ranking was the most stable because no differences were found between sessions, followed by the VAS and the Likert (ordinal) scales, which proved to be the least reliable of them because significant differences were found between trials in overall comfort.

Most reported studies that used ordinal scales (e.g. Hennig *et al*., 1996; Kelaher *et al*., 2000) assessed only 'overall' footwear comfort, but the literature suggests that dividing the shoe into regions, allows a more comprehensive understanding behind comfort perception in relation to a particular shoe. Au and Goonetilleke (2007) reported that an uncomfortable shoe may only be uncomfortable in some regions, whereas in other regions there may be good fit – this is called 'degree of poor fit'. They added that it is also important to bear in mind that the perception of comfort in footwear will change after a period of use and that the toe and arch regions have a greater need for perfect fit.

As it can be seen from Table 3.5, the VAS is the most frequently used way of assessing footwear comfort in recent studies. Mundermann *et al.* (2002) developed a 0-150 mm VAS which proved to be reliable when a control condition is included and an average comfort rating of 4-6 sessions is used. This scale has only its ends labelled ('not comfortable at all' and 'most comfortable condition imaginable') and has been used in other studies that also report good reliability (Yung-Hui and Wei-Hsien, 2005). Finally, to obtain consistent results from the VAS, written instructions must be provided to every participant to ensure the differences in assessments between and within individuals are eliminated.

In addition to comfort, thermal sensation is an important variable used to determine thermal comfort and thermal comfort is a major determinant of the individuals' thermoregulation (Lee *et al*., 2010). The use of clothing, especially in physical activities, implies changes in thermoregulation, meaning that analyses of footwear/insole comfort often do not, but could, include evaluation of the thermal status of the foot. While the VAS is most frequently used to estimate footwear comfort, for thermal sensation Likert scales are more often reported, although the VAS is also utilised. Of the various scales developed, one in particular is a 7-point Likert scale (from 'hot' to 'cold') reported by the International Organization for Standardisation (ISO 7730, 1994) to form part of a predicted mean vote thermal comfort index. The standards for thermal comfort developed by the ISO include the methods and existing data that are more recognised internationally.

In conclusion, the VAS appears to be an appropriate scale for measuring shoe comfort, as it has been shown to be reliable and correlations with the variables that are on continuous scale can be conducted. However, it is important to assess different regions of the foot and to provide written instructions for the participants. Finally, analysis of the thermal sensation should also be considered, especially when evaluating footwear during prolonged physical activity, as it is associated with individuals' thermoregulation.

Table 3.5. An overview of the advantages and disadvantages of main methods to assess comfort in recent studies.

Method		Components measured	Advantages	Disadvantages	Example(s) in the literature
Continuous	150 mm visual analog scale	Running shoes, inserts, orthotics	Parametric statistical analysis can be conducted, correlations between comfort and variables that are measured on continuous scales can be performed.	On a continuous scale, individuals can be unsure about the meaning of a rating, if only the ends of the scale are labelled. Also, it is more difficult obtain 100% replicability.	Mundermann *et al.* (2002); Mundermann *et al.* (2003b); Mundermann *et al.* (2004).
	100 mm visual analog scale				Hansen *et al.* (1998); Mundermann *et al.* (2001); Clinghan *et al.* (2007); Davis *et al.* (2008); Pallari *et al.* (2010).
Ordinal	Modified Borg 15-point perception scale	Shoes, insoles	Most or all the numbers are labelled (depending on the type of ordinal scale) being easier to rate.	Comfort is not indicated in an absolute sense. Due to discrete spacing of ratings, small differences between conditions cannot be detected. Can lead to errors in correlations between comfort and other variables that are measured on continuous scales (Mundermann *et al*., 2002). Finally, this scale depends on the wording used to label each number.	Hennig *et al.* (1996). However, they have assessed footwear cushioning, rather than comfort.
	Modified Borg 10-point scale (scaled as from 1 to 10)				Miller *et al.* (2000).
	7 point Likert scale				Goonetilleke (1999); Kelaher *et al.* (2000).
Ranking	Asking to pick one pair of shoes as preferred model.	Running shoes, insoles	It simulates the actual footwear purchase experience. Useful in determining which shoe/insert is the most comfortable when choosing from a limited number and when they are all undesirable or desirable (Mills *et al*., 2010).	It only limits the choices to the ones available for the research. It does not indicate how much the condition selected is comfortable nor even if comfortable at all.	Kong and Bagdon (2010).
	Comparing 4 types of insoles and ranking 1-4 as the most/least comfortable.				Chen *et al.* (1994).

3.3.2. Performance

Performance can be defined as:

"The result of a physical activity measured in time, distance, work, or a similar quantity." (Nigg and Segesser, 1992).

In the case of running, performance is mainly calculated as the time required to cover a given distance. Improvements in performance are more crucial for athletes as a millisecond can be the differential between gold and silver medals, although recreational runners may also have an interest in running faster. The quantification of running performance is often divided into anaerobic (i.e. sprint) and aerobic (i.e. long distance running). Considering anaerobic performance, it can be measured by using vertical jumps. For example, Stefanyshyn and Nigg (2000) reported that stiffer footwear at the metatarsophalangeal joints (MPJs) increases jump height. In this case, the shoe sole must be stiff enough in order to absorb energy at the MPJs. According to Stefanyshyn and Fusco (2004), stiffer shoes can also reduce sprint time by up to 0.69%. The most usual way of assessing aerobic performance in studies involving shoes and orthoses/insoles is by measuring oxygen consumption, often referred as running economy (RE). Running economy is defined as the rate of oxygen consumed (VO_2) during submaximal running at a given treadmill velocity (Conley and Krahenbuhl, 1980; Roy and Stefanyshyn, 2006). The less VO_2 consumed per unit of body mass per time, the more efficient the runner and, thus the better the performance (Morgan and Craib, 1992). In a review of the literature, Nigg (2001) concluded that less oxygen was required when the subjects were running in more comfortable shoes. This can be partially explained by the fact that the eccentric contraction of muscles has an important role in reducing shock attenuation (Frederick *et al.*, 1983). Therefore, having more cushioning (shock absorption) in the shoe means less work for the musculature which in turn improves running efficiency. This can be evidenced in a study by Clarke *et al.* (1983a) of 10 male runners where they employed shoes with a variety of hardnesses. They found that with harder shoes, individuals exhibited greater knee flexion and therefore that vertical impact peak forces did not significantly change (knee flexion 'masked' them) and with increased knee flexion, extra work is required by the thigh muscles, decreasing performance. These findings are in agreement with Nigg *et al.* (1987) who reported that changes in midsole hardness does not imply an increase in impact force peaks: a change in hardness does not mean better cushioning and reduced impact forces.

Although RE has been used to measure performance, the disadvantages of this test are the many variables that need to be controlled to obtain reliability. For instance, there are daily within-subject variations, so that the tests usually have to be duplicated to achieve repeatability (Williams *et al*., 1991). Also, other variables have to be controlled to obtain reliable outcomes (Williams *et al*., 1991):

- treadmill accommodation – individuals change their gait when running on a treadmill, thus they have to get accustomed to the equipment before the test;
- time of day – there are within-day O_2 variations due to circadian fluctuations. In this case, the test should take place at the same time/period of the day;
- test equipment – there are variations between equipment from different manufacturers;
- footwear – the design and weight of footwear will affect the aerobic demands of running.

Running with orthotics is reported to generally increase the aerobic demands of running (Hayes *et al*., 1983) and this is likely to be due to the weight that an orthosis adds. Mass of the shoe is influential, as an additional mass of 100 g corresponds to an extra work of around 1% of the maximal speed (Nigg and Segesser, 1992). Also, in a study of 22 male runners, Burkett *et al.* (1985) found an increase in absolute VO_2 as the mass of the orthotic increased. Therefore, it is not known whether orthoses do improve running economy, but if they do, this improvement appears to be negated by the additional cost associated with the mass of orthotics (Burkett *et al*., 1985).

In summary, performance in running can be measured aerobic and anaerobically. The most common way of assessing aerobic performance is by assessing the oxygen consumption (running economy). Using this well established method, several variables (e.g. duplication of the test and time of day) have to be controlled to ensure reliability and repeatability of the test.

3.3.3. Evaluation of the lower extremity biomechanical variables

As reported in Chapter 2, some of the biomechanical variables that provide valuable information about the lower extremity are: plantar pressure, vertical ground reaction force and knee and ankle kinematics. These will be critically discussed in the next sections.

3.3.3.1. Plantar pressure

Pressure, or stress, is defined as the force (in Newtons) per unit area (in cm^2). It can be tensile or comprehensive depending on the mode of loading and its unit is the pascal (Pa) (Rodgers and Cavanagh, 1984). In the case of plantar pressure, the stress is compressive and the force measured by a sensor is vertical, or the force that is perpendicular to the surface. Plantar pressure is a good predictor of cushioning and comfort, but it is more associated with comfort when walking than running (Chen *et al*., 1994; Hennig *et al*., 1996; Jordan *et al*., 1997). The difference between walking and running can be partly explained by the force-time curve that characterises each of them. For walking, the vertical component displays a 'camel' type curve, whereas for running the typical curve is a 'parabolic' type (Nigg *et al*., 1986).

Plantar pressure can be measured using platform or in-shoe sensors. According to Orlin and McPoil (2000), both approaches have the same limitation of providing only the vertical force. In some applications the fore-aft and medial-lateral shear are also important. For example, they are thought to contribute to the development of plantar ulcers in individuals with diabetic neuropathies. The main advantage of the platform approach is that a greater number of sensors that are always positioned in parallel to the surface, measuring a true vertical force (Orlin and McPoil, 2000). On the other hand, the platform induces the individual to 'target' the device to step on it. When targeting, the person may modulate the natural gait style, leading to unreliable and inconsistent data. The 'in-shoe' approach provides the relationship between the shoe and foot, whereas the platform is more used to capture barefoot data. As one of the objectives of this chapter is to describe and critically discuss some of the commonly used methods for evaluating footwear in terms of biomechanical variables, only the in-shoe approach will be considered for further discussion. With this method, plantar pressure data provides important information regarding the effect of many types of interventions such as orthoses, footwear, insoles and the pressures applied to specific locations of the foot.

Table 3.6 summarises applications and methods of measuring plantar pressure encountered in the literature and their main findings. It can be noted that plantar pressure is more often recorded during walking, because this type of assessment is frequently used to measure the outcomes of an intervention in clinical and rehabilitation areas. When recording plantar pressure during waking, a frequency of 50-100 Hz is enough to provide reliable results, whereas in running, values from 200 Hz should be considered (e.g. Hodge *et al*., 1999 and House *et al*., 2002).

Dividing the foot into many regions for data analysis helps with an understanding of an intervention (e.g. orthotics) in a specific group of individuals, although the actual number of regions depends on the application. Often the forefoot region is divided into regions because it is the main load-bearing area under the foot. Also, the heel, midfoot and forefoot experience different loadings and phases of the ground contact: the heel absorbs the shock during the impact, the midfoot provides support during the midstance and the forefoot provides guidance for the toe-off.

Table 3.6. Examples of application methods of obtaining in-shoe pressure measurement systems and their main findings.

Authors	Sample	Device(s) measured	Equipment	Recording frequency (Hz)	Number of regions	Activity	Main finding
Chen *et al.* (1994)	Physically active males (n=14)	Insoles	EMED	Not provided	8	Walking and running	Plantar pressure was more sensitive to changes in comfort during walking than running.
Lord and Hosein (1994)	Diabetic patients (n=6)	Custom-moulded inserts	F-Scan	50	12	Walking	Plantar pressure was significantly reduced by molded inserts.
Hennig *et al.* (1996)	Male runners (n=14)	Running shoes	Halm PD-16 (eight capacitance transducers)	1,000	8	Running	Plantar pressure may be an important indicator for the perception of cushioning.
Kato *et al.* (1996)	Diabetic patients (n=7)	Orthotics	F-Scan	Not provided	Not provided	Standing	The F-Scan system is very useful for the design of orthoses.
Hodge *et al.* (1999)	Rheumatoid arthritis suffers (n=12)	Orthotics	Pedar	50	10	Walking and standing	All orthotics tested reduced plantar pressure under the 1st and 2nd metatarsal heads. A significant correlation was detected between pain and pressure under the 2nd metatarsal head.
House *et al.* (2002)	Injury free recruits (n=9)	Insoles	Parotec (Paramed, Germany)	250	2	Running	An insole that is able to reduce peak pressures during running when new will continue to do so after a degradation of 100-130 km of running.
Guldemond *et al.* (2006)	Ten women without history of foot pathologies	Orthotics	Pedar	50	11	Walking	The four orthoses tested in the study showed increased total contact area and lower pressures in comparison to the shoe only.
Clinghan *et al.* (2007)	Males without gait and lower limb abnormalities (n=43)	Running shoes	Pedar	Not provided	8	Walking	More expensive shoes did not provide better cushioning than the cheaper model from the same brand.
Redmond *et al.* (2009)	Flat-footed participants (n=15)	Orthotics	Pedar	50	5	Walking	Similar changes in pressure was found between customised and prefabricated orthoses in comparison to the shoe alone.
Sun *et al.* (2009)	40-60 year old adults (n=50)	Three-quarter shoe insoles	RS SCAN	Not provided	3	Walking	Shoe insoles which provide arch support and heel cup mechanisms can redistribute the pressure under the plantar surface of the foot by reducing the pressure under the forefoot and heel regions and increasing in the midfoot area.

Table 3.7 also shows the two most used measurement systems to assess in-shoe plantar pressure: the Pedar (Novel, St. Paul, USA) and the F-Scan (Tekscan, Boston, USA). Their popularity can also be evidenced by a publication from Hsiao *et al.* (2002) that thoroughly compared the two. There are two fundamental differences between them: (1) the insole sensor thickness and (2) the number of sensors (resolution).

Table 3.7. Comparison between the Pedar and F-Scan in-shoe plantar pressure systems. Information extracted from Lord and Hosein (1994), Hsiao *et al.* (2002), Clinghan *et al.* (2007) and Tekscan (2008).

System	Resolution	Insole thickness	Main advantages	Main disadvantages
Pedar	1 sensor per cm^2	2 mm	Sensors have more durability, because the insole is thick.	The thicker the insole, the more likely it is to influence the outcomes – individuals can alter the gait.
F-Scan	4 sensors per cm^2	0.18 mm	Can be trimmed to any shoe size. Has better resolution.	Thin sensor has less durability (making it less cost-effective) and can form creases around the heel cup and forefoot, breaking the printed circuit.

Other systems to measure in-shoe plantar pressure include: the EMED (Chen *et al*., 1994), the Halm PD-16 (Hennig *et al*., 1996) and the RS Scan (Sun *et al*., 2009). According to Chen *et al.* (1994), the EMED insole pressure measuring system is a device based on the capacitance principle; it is 2 mm thick and has 85 sensors. However, no further detail was found by the author about the EMED or the RS Scan. Hennig *et al.* (1996) reported that the Halm PD-16 is a system consisting of eight discrete capacitance transducers. The disadvantage of using these kinds of transducers to measure plantar pressure is that they have to be taped under the foot with adhesive tape and the specific areas of the foot have to be identified by palpation. This procedure requires more time to set up and can lead to errors if the foot structures are not accurately identified by the investigator. Finally, the Halm PD-16, the EMED and the Pedar all are all 2 mm thick, which is high for an in-shoe device.

According to Hsiao *et al.* (2002), in general the factors that influence data collection using the F-Scan and the Pedar plantar pressure systems include:

- following a manufacturer specified callibration procedure;
- applied pressure level on calibration and during data collection;
- duration of pressure application; and
- insole age of use.

However, even adopting strict guidelines in data collection, measurement errors can be as much as 14% at low force ranges (735 ± 880 N) using the F-Scan (Woodburn and Helliwell, 1996). Further limitations of the in-shoe pressure measurements systems depend on the equipment used, type of activity recorded, recording frequency and so on.

In conclusion, the systems to measure plantar pressure are: platform and in-shoe. While the former is more often used capture barefoot pressure, the latter can be effective in providing information about the relationship between the foot and the shoe/insole. The two most popular in-shoe systems (Pedar and F-Scan), both offer advantages and disadvantages, therefore it is important to adhere to strict guidelines when collecting data to ensure reliability. The methodology employed (the system, recording frequency and number of regions of the foot) depends of the type of analysis: the activity (running/walking), research sample (individuals with/without abnormalities) and intervention (orthotics/footwear).

3.3.3.2. Ground reaction force

When the foot makes contact with the ground, forces act from the ground to the foot and vice versa, following Newton's third law: "for every action there is an equal and opposite reaction" (Hintermann and Nigg, 1998). To estimate the level and which areas of the lower limb forces are being applied as well as the centre of pressure path underneath the shoe, ground reaction force (GRF) data is collected with a force platform (FP) (Cavanagh, 1989). It provides information about the vertical, backward-forward and side to side (medial-lateral) forces. However, the vertical component is more frequently discussed in research, because of its magnitude that dominates the resultant GRF; and because its force-time history is more straightforward than the other two components, being easier to quantify for comparative purposes (Miller, 1990). According to Miller (1990), the convention of the direction of the GRF components assumes that the individual is running on a horizontal surface. The force plate differs to the pressure plate because it does not estimate the contact area to measure stress. Pressure plates give information about loading distribution in various anatomical regions, rather than just the resultant force acting on the whole foot (Rodgers and Cavanagh, 1984). The FP is useful for displaying the behaviour of the forces underneath the shoe and in which direction they are being exerted (McKenzie *et al*., 1985). In running, these forces vary according to the gait pattern and speed of the individual.

3.3.3.3. Gait data acquisition

In order to have a good understanding of the lower extremity biomechanics, collecting kinematic and kinetic data of the lower limbs is essential. This is feasible by utilising a motion capture system, which visually records the individual's movement during physical activity (running, in the case of this thesis) and transforms it into a digital model. There are many motion capture systems available on the market, including Apas (Ariel Dynamics), CODA (Charnwood Dynamics Ltd), Elite (Bioengineering Technology and Systems), Optotrak (Northern Digital, Inc.), Peak (Peak Performance Technologies, Inc.), Qualisys (Qualisys Medical AB, Gothenburg, Sweden), Raptor-E (Motion Analysis) and Vicon (Vicon Motion Systems Ltd.) (Civek, 2006). Among these, the most common ones used for gait analysis are: Raptor-E, CODA and Vicon. Table 3.8 displays some specifications of the systems from these companies. Although the author researched for the approximated costs of these systems for comparison, they could not be found from a reliable source.

All of these systems are expensive and from those described in Table 3.8, the Vicon system is discussed further as it is available for the proposed research. The Vicon Motion System® is a well known motion capture system for recording body movement. It requires reflective markers that can vary in diameter (depending on the application), but usually they are 12-25 mm wide and have to be placed on the body.

Table 3.8. Manufacturers' specification for selected parameters (adapted from Richards, 1999).

Company	Motion Analysis	Charnwood	Vicon
System	Raptor-E	CODA	Vicon MX
Marker system	Passive (the markers reflect light back to the cameras)	Active (lights are pulsed by the markers and captured by the cameras)	Passive (the markers reflect light back to the cameras)
Accuracy	0.1 mm	0.1 mm	Not found
Max cameras	Unlimited	6 Codas	Unlimited
Max markers	400	56	Unlimited
Calibration	Using a cube and a wand	Factory	Using wand or frame
Lighting (Richards, 1999)	Red/infra red	Active infra red	Red/infra red
Max Speed (fps)	480 in higher resolution	100 with 56 markers	500 in higher resolution
Main advantages	• Can track a high numbers of markers. • System records in high frequency.	• Active markers are identified more precisely. • Calibration is done at the factory, reducing substantially the chance for errors.	• Has no limit of markers. • System records in high frequency.
Main disadvantages	• Passive marker systems require post editing by the systems. • In passive systems, markers can merge if placed closer than 2 mm.	• Low number of cameras, being more prone to the system not tracking the marker because of a shadow. • Records in slower frequency and supports fewer markers simultaneously.	• Passive marker systems require post editing by the systems • In passive systems, markers can merge if placed closer than 2 mm.

The markers are placed on pre-defined anatomical locations which depend on the mathematical model used for processing data. The selection of the appropriate multi-segment model for processing data is essential to ensure the model is efficient. There are a variety of models for calculating joint centres and consistent and accurate marker placement is essential to ensure the data is reliable. Once the markers are placed, the system tracks them in the space using cameras and their exact XYZ coordinates are identified in a given capture volume. With the use of 3 markers and anthropometric measurements (e.g. leg length, knee width), the system defines each body segment. Accuracy in taking the anthropometric measurements and the placing of the markers are the main sources of error. The Vicon system uses hardware (data station, cameras, markers, etc.) and software applications for the complete control, analysis and manipulation of motion capture (Vicon, 2002). According to Vicon (2002), the main applications for this sort of motion capture are:

- medical assessment of movement disorders;
- understanding of athlete techniques;
- generating lifelike character animation for movies, video games, broadcast and webcast; and
- incorporating motion into virtual environments for engineering design.

Plug-in Gait lower body marker set

Among the existing biomechanical models of marker sets for gait data acquisition, Vicon's Plug-in Gait (PiG) is one of the most common, used in the majority of clinical gait analysis laboratories, widely used in the research community and its main advantage is its profile of being an easy to use plug in (Vicon, 2008). It has been validated through many research publications, such as Kabada *et al.* (1990) and Davis III *et al.* (1991) (Vicon, 2008). It is based on the Newington-Helen Hayes gait model and allows the calculation of joint angles, moments and power with inverse dynamics. With this biomechanical model, it is possible analyse the entire body by placing markers on the individual's upper limbs, head, trunk and so on, or by using a lower body marker set, when only the movements of the lower limbs are required for the analysis. It is also important to highlight that the reflective markers have to be accurately placed on pre-defined landmarks. Depending on the joint assessed, even a slight shift in the marker position can produce unreliable results. This is a potential problem, particularly where bony prominences and axes are difficult to be identified by palpation, for example in overweight or obese individuals. Therefore, when collecting data from individuals on different occasions, it is important to adopt the same protocols to ensure repeatability of their placement. In this sense, recent studies have introduced equipment which aims to help the accuracy of the marker placements in different laboratory sessions (Telfer *et al*., 2010). Marker placement accuracy is the main limitation of the motion capture systems of this kind.

In summary, the calculation of joints' kinematics and kinetics using motion capture systems is well documented in the literature. The most common ones for gait analysis are the Motion Analysis (e.g. Raptor-E), Charnwood (e.g. CODA) and Vicon (e.g. Vicon MX), with the Vicon being the system available to the author. The Vicon's PiG multi-segment model has been tested and validated in different research studies and is considered an easy to use plug-in, but its main sources of limitation are: (1) lack of accuracy in marker placements; (2) potential inaccurate limb measurements; and (3) observer-dependent variability in multi maker placement.

3.4. Conclusions

This chapter reviewed the methodological approaches for the research on footwear personalisation. The following conclusions are made.

- The methods for a potential personalisation process for the development of footwear, specifically insoles, have been identified: foot capture and AM.

- For foot capture, a combination of 3-D scanning and taking anthropometric measurements can be important to specify the optimal properties (e.g. insole material).
- AM technology shows promise in the development of personalised footwear mainly because of its tool-less capability, despite current limitations (mainly the high costs and materials available). This technology requires the methods of reverse engineering, but the exact actions for insole design are not well understood.
- Visual analog scales are appropriate for assessing comfort as they have been shown to be reliable and because they allow correlations with the parameters that are on continuous scales. Also, thermal sensation should also be assessed, as it is associated with individuals' thermoregulation.
- Running economy is a well established method for assessing aerobic performance in running (via oxygen consumption), but it requires the control of several variables (e.g. duplication of the test) to ensure reliability and repeatability of the test.
- With regard to the lower extremity biomechanics, analysis of plantar pressure distribution, GRF and knee and ankle kinematics are frequently conducted. They provide information about the interaction between the ground, footwear and locomotor system.

The findings of this chapter indicate the need for a pilot study to explore the footwear personalisation process further and test the materials and methods identified in order to rationalise the techniques for specifying and evaluating the footwear.

Chapter 4: Exploratory study of the personalisation process

4.1. Introduction

It has been identified from the literature that footwear ideally needs to be personalised to provide optimum fit, comfort, performance and injury prevention. Methodological approaches for the research on footwear personalisation using additive manufacturing (AM) have also been reviewed and a possible personalisation process has been identified for the development of insoles in terms of foot capture (3-D scanning and anthropometric measurements) and AM technology (insole and specialised design). Ways of evaluating footwear/insoles in terms of comfort, performance and lower extremity biomechanical variables have also been identified: visual analogue scales (VAS) to measure comfort and a Likert scale to assess thermal sensation, running economy (RE) to measure performance, and plantar pressure distribution, ground reaction force (GRF) and kinematics of the knee and ankle to assess lower extremity biomechanics. Table 4.1 summarises the variables of interest identified in Chapter 3 and that will be explored in the pilot study.

Table 4.1. Variables of interest in evaluating footwear/insoles.

Type	Variable of interest	Equipment	Rationale
Psychological and neuro-physiological	Discomfort ratings	Foot discomfort: VAS; thermal sensation: Likert scale	Comfort is the main aspect that an individual takes into account when purchasing a footwear (Cavanagh, 1980). Footwear discomfort prevents individuals performing activities for a prolonged time.
Physiological	Oxygen consumption	Ultima CardiO_2	Studies suggest that orthoses are good for improving performance – by reducing muscle work and increasing self-perceived comfort (Nigg *et al.*, 1999; Mundermann *et al.*, 2001).
Biomechanical	Knee and ankle kinematics	Vicon System	Associated with knee overuse injuries and patellofemoral pain syndrome (Stacoff *et al.*, 2000; Nigg, 2001).
			Excessive rearfoot eversion is linked to the development of various running injuries, including knee injuries (James *et al.*, 1978; Smart *et al.*, 1980).
	Vertical ground reaction force	Kistler force platform	Thought to be linked to some overuse running injuries (Hreliac *et al.*, 2000).
	Peak plantar pressure distribution	F-Scan mobile	High values of plantar pressure are related to increased discomfort and injuries (McKenzie *et al.*, 1985; Jordan *et al.*, 1997).

4.2. Aim and objectives

Part of the focus of this thesis is to develop and explore footwear personalisation using AM and to evaluate such footwear in terms of comfort and health. A pilot study was therefore conducted to further explore and refine the research methods and the personalisation process described in Chapter 3, addressing the following objective:

- to develop and explore the process that delivers personalised insoles using AM.

Finally, the pilot study provided an opportunity to explore and try out the equipment, materials and techniques required for the personalisation process in the laboratory environment.

4.3. Research method

4.3.1. Sampling strategy

Sample size was defined considering the following aspects: previous studies that collected data of similar nature (from runners and evaluating footwear/inserts) and the practical issues involved (i.e. financial and time constraints). Six participants were recruited using convenience sampling and snowballing techniques. Inclusion criteria were:

- 18 to 65 years old;
  Rationale: younger (< 18 years) or older (> 65 years) individuals are considered vulnerable population groups by the university's Ethical Advisory Committee.
- Run at least 5 kilometres per week;
  Rationale: the minimum of 5 kilometres was established to recruit individuals that run regularly, meaning that they have experience with the usage of running trainers. Also, it was aimed to recruit recreational runners and not elite athletes.
- Have no reported musculoskeletal symptoms or injury in the last 12 months;
  Rationale: the reason for this was to ensure that the individuals were healthy at the time of the study. This was important for three fundamental reasons. Firstly, to make sure the participants did not need medical help nor had severe anomalies of the lower extremities. Secondly, to ensure that the individuals would perform a 'natural' run, without altering the gait pattern in the case of recovering from injury or experiencing pain. Finally, to certify that the runners would not have their perceived sensations impaired or changed because of an injury or pain.

- Have not used an orthosis in the last 12 months;
  Rationale: to ensure individuals did not have severe anomalies of the lower extremities and that they did not have experience with customised inserts which could influence the variables analysed.

Ethical approval was issued on 6 July 2008 by the Ethical Advisory Committee from Loughborough University under the Ref No: R08-P86.

4.3.2. Study design and rationale

The first contact with the 6 participants was via e-mail, telephone or personally, with a brief explanation of the 'Elite to High Street' project and the nature of this pilot study. Following that, a participant information sheet (Appendix 4.1) was given. If the individual agreed to take part, their shoe size was taken and they were asked to attend three laboratory sessions. A repeated measures experimental design was utilised to minimise potential variation (error) by controlling individual variability (Fallowfield *et al*., 2005). New Balance trainers (model: NB-757, Neutral Cushion) were recruited and two conditions, control (shoes + original insole) and personalised (shoes + personalised insole), were compared through single blind trials to avoid any intentional or unintentional behaviour from the participants that might be prejudicial to the outcomes of the study (Fallowfield *et al*., 2005).

Figure 4.1 summarises the personalisation process explored in the pilot and how it was evaluated. The main form of evaluation was through the discomfort, performance and biomechanical data collected. For example, correlations were conducted to detect relationships between the anthropometric measurements and the dependent variables (discomfort, performance and biomechanics). If existing, these relationships could potentially indicate which individuals benefited from using the insoles.

Element	Sub-element	Equipment (E) and Actions (A)	Evaluation
Foot Capture	 3-D scanning	**E:** 3-D scanner **A:** Scanning plantar surface of the foot to obtain point cloud data.	• Time to position and scan the foot. • Compatibility and quality of the scan data. • Discomfort, performance and biomechanics to measure the foot position (e.g. if foot has to be captured in a different position).
	 Anthropo-metric measurements	**E:** Anthropometer, caliper and tape measure **A:** Manual measurement of lengths, widths, heights and girths of the foot.	• Usefulness to design of the insoles. • Correlations between the measurements and the discomfort, performance and biomechanical parameters.
Additive manufacturing technology	 Insole design	**E:** Magics software **A:** Cleaning the point cloud data, smoothing, thickening and converting into an STL file.	• Time to design the insoles. • Capability of the Magics software in the design. • Discomfort, performance and biomechanics to assess the insole design (e.g. if data has to be manipulated in a different way).
	 Manufacture of the parts	**E:** LS machine **A:** Manufacturing the parts from the STL files, using Nylon 12 and AM technology.	• Time to manufacture the insoles. • Durability of the material Nylon 12 (assessed visually for sings of crack and wear). • Material in terms of discomfort, performance and biomechanics.

Figure 4.1. Flow chart showing the insole personalisation process explored in the pilot and how it was evaluated.

The author discussed the research methods with 3 individual podiatrists prior to the start of the study. Important guidance included that: (1) checking for foot anomalies requires practice, so the study's inclusion criteria should not be based on physical assessment of the participants' feet, unless the researcher could be trained to do so; (2) the ideal way to scan the foot is dynamically, but this not being possible, the non-weight bearing position is one of the most used by podiatrists; (3) the arch and heel cup support offered by insoles manufactured using the non-weight bearing foot capture position could provide benefits in reducing the risk of injury by improving lower extremity alignment and reducing the eversion values.

4.3.2.1. Session 1: foot capture

On arrival, the procedures were discussed with participants. A physical activity and heath screen questionnaire (Appendix 4.2) was completed. After that, a consent form was given, including gaining permission to record them using the Vicon System, scan their feet, and informing them that they may withdraw at any time, without having to give any reason for doing so (Appendix 4.3).

A block (dimensions: 37 cm x 62 cm x 15 cm), was constructed to facilitate taking the manual anthropometric measurements of the foot. Participants were asked to stand on the block, with their feet shoulder width apart, in a bilateral stance (Figure 4.2). Markers were placed on the dorsum of the foot at 50% of foot length, medial and lateral aspects of the 1st and 5th MPJs, respectively, and on the most anterior-inferior portion of the navicular.

Figure 4.2. Participant standing on the block constructed to facilitate taking anthropometric measurements.

As the literature reports no significant differences between the left and right foot for both male and female individuals (McPoil *et al*., 2009), detailed anthropometric measurements of right foot only were taken (Table 4.2 and Figure 4.3).

Table 4.2. Anthropometric measurements taken on first session of the pilot study.

	Measurement	Description	Equipment	Reference
a	Foot length (1st digit)	The most prominent point of the first digit to the most posterior projecting point on the heel.	anthropometer	Hawes and Sovak (1994); Williams and McClay (2000)
b	Foot length (2nd digit)	The most prominent point of the second digit to the most posterior projecting point on the heel.	anthropometer	Hawes and Sovak (1994)
c	Foot length (5th digit)	The most prominent point of the firth digit to the most posterior projecting point on the heel.	anthropometer	Hawes and Sovak (1994)
d	Metatarsale tibiale length (truncated foot length)	From the first MPJ to the most posterior projecting point on the heel.	anthropometer	Hawes and Sovak (1994)
e	Metatarsale fibulare length	From the fifth MPJ to the most posterior projecting point on the heel.	anthropometer	Hawes and Sovak (1994)
f	Foot breadth	Between the first and fifth MPJs.	caliper	Hawes and Sovak (1994)
g	Heel breadth	Measured with compression to the bony surface at the point of maximum hell width, 2-3 mm above the standing surface and approximately 3 cm anterior to the pternion.	caliper	Hawes and Sovak (1994)
h	Dorsum height at 10%	Floor to the dorsum of the foot at 50% of foot length.	anthropometer and weight scale	Williams and McClay (2000)
h	Dorsum height at 90%	Floor to the dorsum of the foot at 50% of foot length.	anthropometer and weight scale	Williams and McClay (2000)
i	MPJ height	Floor to the superior point of the first MPJ.	anthropometer	Hawes and Sovak (1994)
j	Hallux height	Floor to the superior surface of the hallux.	anthropometer	Hawes and Sovak (1994)
k	Navicular height	Floor to the most anterior-inferior portion of the navicular.	anthropometer	Williams and McClay (2000)
l	MPJ girth	Encompassing the first and fifth MPJs.	retractable tape	Hawes and Sovak (1994)
m	Mid arch girth	Measured in the frontal plane passing through the dorsum.	retractable tape	Hawes and Sovak (1994)
n	Heel girth	Encompassing the dorsum and the point of distal heel contact on the standing surface.	retractable tape	Hawes and Sovak (1994)

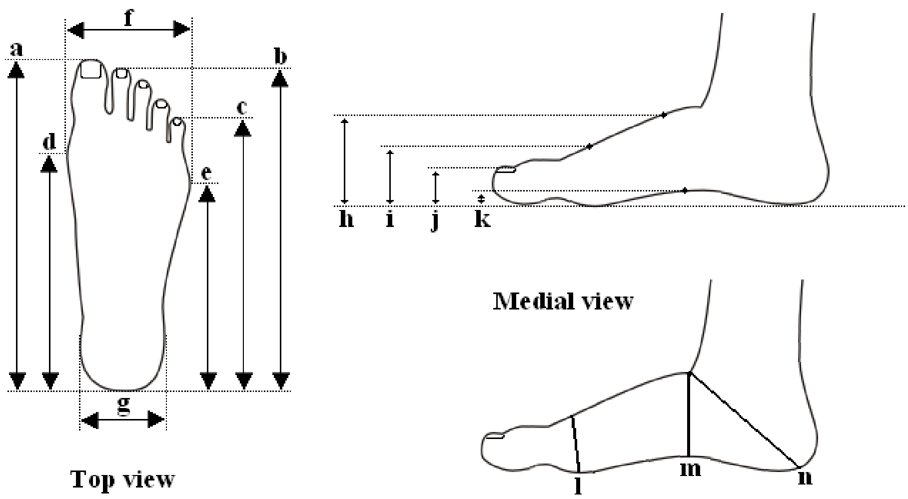


Figure 4.3. Anthropometric measurements of the foot as described in Table 4.2.

As stated in Table 4.2, the two dorsum height measurements were taken at 10 and 90% of weight bearing, by asking the participants to stand with one foot on the block and the other foot on a weighing scale of the same height (Figure 4.4). They were asked to add or release load from the right leg (on the weighting scale) to reach the desired percentage.

Figure 4.4. The set up showing scale (left) and a block (right) to facilitate taking anthropometric measurements.

The following calculations enabled the classification of individuals according to their medial longitudinal arch, providing an indication of low, normal or high arched feet.

- 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), see Chapter 2.

Following these manual measurements, participants were asked to sit on chair, fully extend their knee and dorsiflex the foot in a way that the plantar surface of the foot became parallel with the glass of the scanner (Figure 4.5). Then, the plantar surface of both feet were scanned in a non-weight bearing position, using a three-dimensional laser scanner (model: eScan 200; 3D Digital Corporation, Newtown, USA). According to the manufacturer, the depth of field of this scanner is between 300 – 650 mm; its resolution between 0.135 – 0.210 mm and scanning deviation between 0.150 – 0.250 mm, both respectively to the depth of field. Also, the scanner's field of view is 40 degrees. Finally, the scanner was configured to have 300 lines per scan (which can be set between 200 – 1000 lines) as a higher number of lines would increase the scanning time and the participants could get fatigued in maintaining a static position for extra seconds. This scanner was on loan from Pro-Fit Technologies (Ravenshead, UK; www.pro-fit-tech.co.uk) for 3 weeks and was the only scanner available at the time of the study.

Figure 4.5. The plantar contour of the foot being scanned.

4.3.2.2. Insole design and manufacturing

After session 1, the personalised insoles were designed by the researcher and manufactured using the facilities of the Additive Manufacturing Research Group at Loughborough University. As discussed previously, any correction of abnormalities would require the involvement of a specialist to assist with the experimental trials, but this was not possible due to time and cost constraints. Hence, data manipulation was performed on the scan data solely to rectify and delete unwanted data, but preserving the geometric accuracy of the scans. At this stage, the insole scans were also marked with a unique number to aid their identification. A depth of 0.5 mm was selected to engrave the surface to avoid perception by the wearer. Appendix 4.4 details the actions taken and stages of the insole design, which were: foot scan data were 'cleaned' to remove any ‘noise’ and unwanted data, smoothed, thickened to a depth of 3 mm in the z direction, engraved and converted in to an stereolithography (STL) file using Magics software (version: 12.0.0.19; Materialise Leuven, Belgium). James Woodburn, Professor in Rehabilitation Studies from Glasgow Caledonian University was one of the podiatrists consulted to discuss the methodology for the pilot study. During the consultation, he recommended a level of hardness for the design of the insoles and an insole thickness of 3 mm achieved this match..

Once the parts were designed, they were manufactured through laser sintering (LS). DuraForm® PA, a Nylon 12 (polyamide) based material was selected, which is a rigid nylon with a hardness classified as Shore D 73 (3D Systems, 2010b). DuraForm® PA was chosen for its durability and as it is commonly used for LS, it is easiest to process and more widely known in the research community. After manufacture, the insoles had to be sanded to remove sharp edges, given that the Magics software did not allow total manipulation of the sharp boundaries into a smooth edge.

In order to ensure a blind trial, that the personalised condition would fit inside the shoe and to provide extra comfort, a microporous polyurethane foam was used to cover both insoles. An illustration of how the two conditions (control and personalised) were constructed can be found in Appendix 4.5. Basically, the personalised condition had to be sanded down to eliminate sharp edges and, after that, both conditions were glued to the foam material. The control insoles were the original ones that come with the shoes, made of a flexible foam material and matched the inside of the footwear from the heel counter to the toe box region. The insoles for the personalised condition were designed to match the form of the participants’ feet (glove fit) and provide support from the heel to the base of the metatarsal heads, but no correction of any lower limb or gait abnormalities. Figure 4.6 shows both conditions used in the experiment.

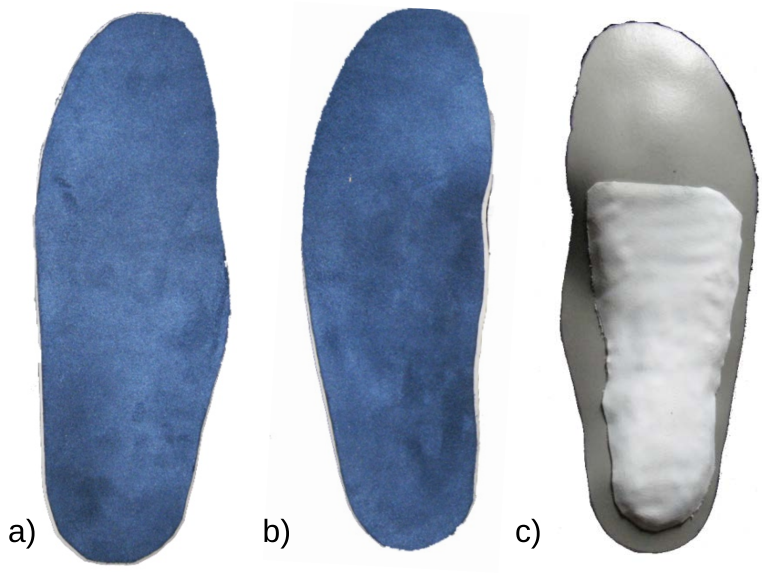


Figure 4.6. a. top view of the control condition. b. top view of the personalised condition. c. bottom view of the personalised condition.

4.3.2.3. Session 2: footwear evaluation (1)

Once the insoles had been constructed, the participants were invited for a second laboratory session. The session was used to collect data on discomfort (VAS), performance (running economy) and biomechanics (plantar pressure distribution). Four days prior to session 2, a sheet containing the guidelines for the physiological testing (Appendix 4.6) was sent to the participants to ensure standard preparation for the running economy trials for more reliable results.

An F-Scan Mobile (Tekscan Inc., USA) in-shoe plantar pressure sensor (N/cm^2) was placed in the shoe, between the insole and the plantar surface of the foot. This sensor has 960 individual pressure-sensing locations before trimming with a spatial resolution of 4 sensors per cm^2, uses resistance-based technology and the insole itself consists of two polyester sheets whose inner surfaces are printed with electrical circuits (Figure 4.7). Sandwiched between the circuits is a semi-conductive ink whose electrical resistance changes inversely proportionally to the pressure applied (Hsiao *et al.,* 2002). The participants were asked to run at the same speed as they do in a training session for 10 meters, repeated 5 times under each condition (control and personalised, 10 times in total) whilst plantar pressure distribution was recorded at 250Hz.

Figure 4.7. The Tekscan in-shoe plantar pressure sensor before trimming.

After that, the running economy trial took place. Participants warmed up for 10 minutes in their own footwear, on a Mercury Med treadmill (H-P-cosmos sports & medical, Nussdorf-Traunstein, Germany) at a self selected speed. They were then encouraged to do some stretching exercises and drink water. During the data collection, they were asked to wear the footwear with one of the 2 running shoe conditions (control or personalised, balanced presentation, randomly assigned) and run for 6 minutes under each experimental condition: 4 minutes to reach a steady state and 2 minutes for data collection. The speed selected was 2 km/h faster than that used for the warm up. Expired air was collected using an Ultima CardiO_2 (Medical Graphics Corporation, St Paul, MN, USA) equipment. The treadmill was set at 1% gradient at all times as this percentage has been shown to most accurately reflect the energy cost of outdoor running (Jones and Doust, 1996). A break of at least 5 minutes was given between runs. At the end of each run on the treadmill for the running economy trial, participants were given a 150 mm VAS to measure self-perceived discomfort (Appendix 4.7). The VAS was similar to one used by Mundermann *et al.* (2002), indicating from ‘the most comfortable condition imaginable’ to ‘not comfortable at all’. Six aspects of the shoe were evaluated: overall, forefoot, midfoot, heel, arch and fit. As reported in Chapter 3, the VAS is an appropriate scale for this kind of assessment. In addition to the VAS, a 7-point Likert (‘hot’ to ‘cold’) thermal sensation scale (Appendix 4.8) was also used as described by the International Organization for Standardization (ISO 7730, 1994) to evaluate thermal sensation. The reason for the thermal assessment was that the individuals were running with devices (insoles) that could potentially affect perspiration of their feet, changing their thermal sensation.

4.3.2.4. Session 3: footwear evaluation (2)

The last session was used for the gait analysis. At the start, participants had 5 practice trials running for 10 meters and landing over a force platform using their own footwear. After that, kinematic data were assessed using a Vicon system, which was the motion capture system available to the researcher at the time. Before the actual data collection, measurements of the participants' leg, knee and ankle were taken as the Vicon system requires the following for data processing:

- mass (in kilograms);
- height (in centimetres);
- leg length (in mm) – measured between the anterior superior iliac spine and the medial malleolus, via knee joint, measured with the participant standing;
- knee width (in mm) – measured as the medio-lateral width of the knee across the line of the knee axis, with the participant standing;
- ankle width (in mm) – measured as the medio-lateral distance across the malleoli, with the participant standing.

Wearing the footwear (with the control or personalised insole randomly assigned), participants had 16 reflective markers (diameter of 14 mm) placed on their lower limbs for tracking 3-D movement, according to the Vicon's Plug-in Gait (PiG) standard lower body modelling (Kadaba *et al*., 1990; Davis III *et al*., 1991). This model allows the calculation of joint angles, moments and power with inverse dynamics and is one of the mostly commonly used techniques for gait data acquisition. Table 4.3 lists the marker set required for the PiG lower body model and describes the anatomical landmarks that they should be placed on, while Figure 4.8 shows an illustration. The heel and toe markers were placed on the trainers at locations that best projected the anatomical landmarks.

Table 4.3. The Plug-in Gait lower body marker set description (Vicon, 2008).

Marker Label	Definition	Position
LASI	Left anterior superior iliac	Left anterior superior iliac spine.
RASI	Right anterior superior iliac	Right anterior superior iliac spine.
LPSI	Left posterior superior iliac	Left posterior superior iliac spine (immediately below the sacro-iliac joints, at the point where the spine joins the pelvis).
RPSI	Right posterior superior iliac	Right posterior superior iliac spine (immediately below the sacro-iliac joints, at the point where the spine joins the pelvis).
RTHI	Right thigh	Over the upper lateral 1/3 surface of the right thigh.

Marker Label	Definition	Position
RKNE	Right knee	On the flexion-extension axis of the right knee.
RTIB	Right tibia	Over the upper 1/3 surface of the right shank.
RANK	Right ankle	On the lateral malleolus along an imaginary line that passes through the transmalleolar axis.
RHEE	Right heel	On the calcaneous at the same height above the plantar surface of the foot as the toe marker.
RTOE	Right toe	Over the second metatarsal head, on the mid-foot side of the equines break between forefoot and midfoot.
LTHI	Left thigh	Over the lower lateral 1/3 surface of the left thigh.
LKNE	Left knee	On the flexion-extension axis of the left knee.
LTIB	Left tibia	Over the lower 1/3 surface of the left shank.
LANK	Left ankle	On the lateral malleolus along an imaginary line that passes through the transmalleolar axis.
LHEE	Left heel	On the calcaneous at the same height above the plantar surface of the foot as the toe marker.
LTOE	Left toe	Over the second metatarsal head, on the mid-foot side of the equines break between forefoot and midfoot.

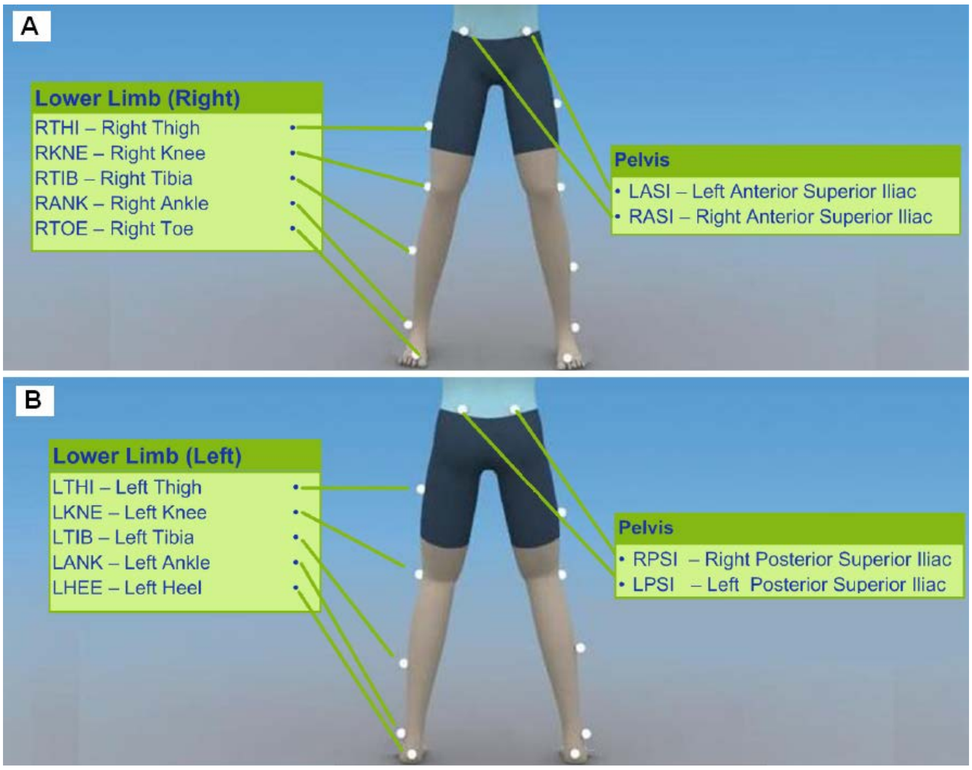


Figure 4.8. Plug-in Gait lower body marker placement. A: front view; B: back view. NB: RHEE and LTOE markers are not identified. Adapted from Vicon (2008).

Participants were asked to run five times under each condition at the same speed as they run in a training session while kinematic data were collected with a 10-camera Vicon MX system (250Hz; Vicon Motion Systems Ltd, Oxford Metrics, Oxford, UK). To capture vertical ground reaction force, a force plate (Type: 9281CA; Kistler Instrumente AG, Winterhur, Switzerland) was used (recording at 500 Hz) and synchronised with the kinematic data. After that, the reflective markers were removed from the body and the

New Balance shoes used in the study (with their original insole) were given to the participants to thank them for their time.

4.3.3. Data analysis

Statistical Package for the Social Sciences (SPSS) software for Windows (Release 15.0, SPSS©, Inc., 2006) was used for all analyses. Significant differences ($p \leq 0.05$) between the two conditions were evaluated using a paired samples Student's *t*-test. According to Fallowfield *et al.* (2005), the paired samples *t*-test is a parametric test more powerful than the Wilcoxon test: it is more likely to detect a difference in the data if there is one. Pearson's product moment correlation coefficient was used to detect relationships between the anthropometric data and the discomfort, performance and biomechanical variables. This test was chosen because is the best known correlation coefficient (Fallowfield *et al*., 2005).

For the purpose of the analysis of the plantar pressure data, the foot was divided into three regions: heel (first 30% of foot length), midfoot (second 30% of foot length) and forefoot (final 40% of foot length). These foot length portions are similar to those reported by other authors (e.g. Redmond *et al*., 2009). Peak mean pressure was measured in each region using F-Scan Mobile Research software (version: 5.72; Tekscan Inc., USA) and provided information about the highest mean pressures under the foot during the ground contact (Figure 4.9). Values for mean contact area of the whole foot were obtained using the same F-Scan software.

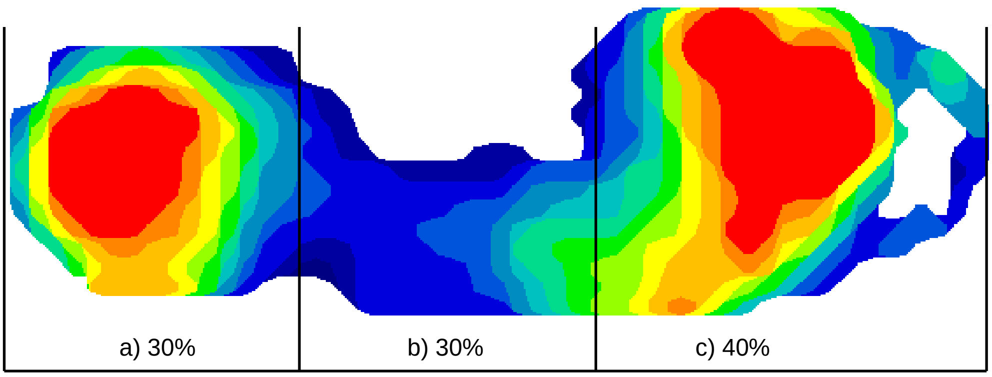


Figure 4.9. Example of a plantar pressure distribution captured using the F-Scan system. Areas in red indicate the highest pressures and areas in blue, the lowest pressures. The foot was divided into 3 regions: (a) heel, (b) midfoot and (c) forefoot.

The biomechanical data collected with the Vicon System and force plate were extracted using the software Vicon Nexus (version 1.5.2; Vicon Motion Systems, Oxford, UK). Because this study was a pilot, only 2 kinematic data types were selected for analysis: tibial internal rotation excursion (TIR) and ankle eversion excursion. Since the foot 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 of motion of the ankle joint), whilst ankle eversion was defined as the frontal plane of motion of the ankle joint. To analyse the kinematics of the ankle, the following definitions were made: (1) foot strike (FS) was the first frame when the GRF ≥ 50 Newtons and was considered the start of the ground contact phase; (2) toe off was the last frame when the GRF ≥ 50 Newtons and was considered the end of the ground contact phase; and (3) excursion was defined as the joint's range of motion during ground contact.

Again, as this study was a pilot, the only GRF variable assessed was impact peak, defined as the first peak in the vertical ground reaction force data (Figure 4.10). The forces were normalised as times body weight (bw). Ground reaction force values were also used to determine the moments of heel strike and toe-off in stance phase.

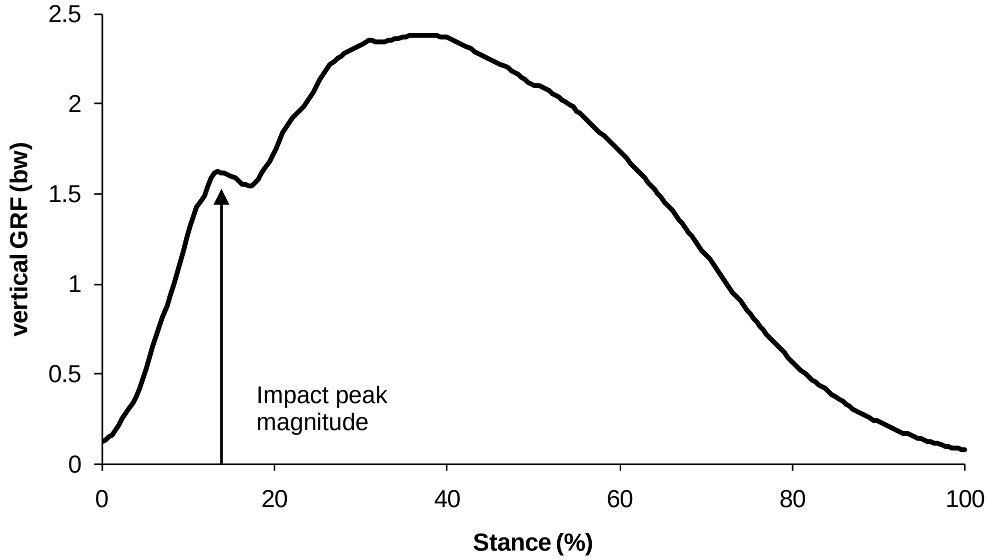


Figure 4.10. Example of a vertical GRF showing how the impact peak was identified.

4.4. Results

The characteristics of the six participants recruited (3 males and 3 females) are described in Table 4.4. They were 25-37 years of age, with different levels of running per week, ranging from 5 to 32.5 kilometres. In this section, the results of the evaluation of the insoles in terms of discomfort, performance and biomechanics are reported, followed by an evaluation of the footwear personalisation process.

Table 4.4. Descriptive characteristics of study participants.

Participant number	1	2	3	4	5	6
Gender	Female	Male	Male	Female	Male	Female
Age (yrs)	29	37	31	31	25	30
Height (cm)	169.6	161	179.3	143.7	176.3	165.1
Body mass (kg)	57.8	66.6	94.4	45.3	69.2	58.2
Shoe size (UK)	7.5	8.5	10	5	8	3.5
Kilometres ran per week	32.5	5	22.5	25	12	5

4.4.1. Discomfort, performance and biomechanics

After the 6-minute run on the treadmill, participants were given a VAS to report on their self-perceived discomfort in 6 aspects of the foot. The mean ratings for discomfort variables were generally low for both conditions (Figure 4.11), and statistical analysis showed no significant differences (p > 0.05).

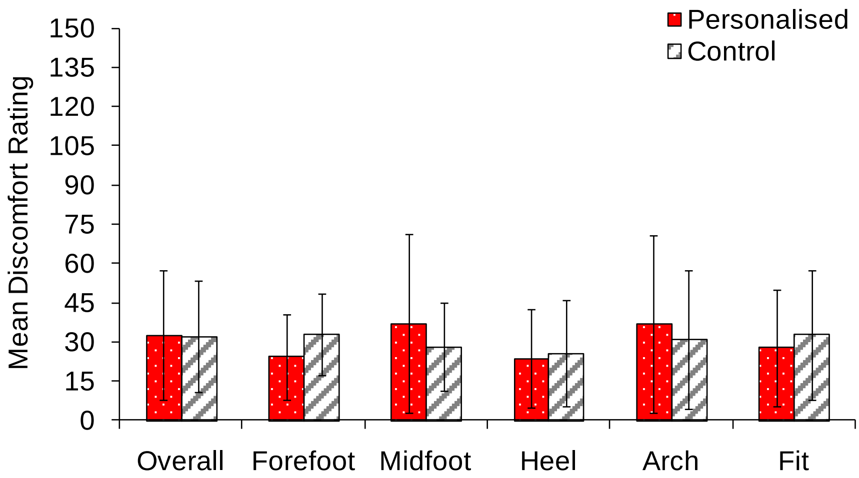


Figure 4.11. Mean discomfort ratings and standard deviation for the two conditions.

After the 6-minute run, participants were also asked about the thermal sensation in their feet. Interestingly, all participants selected exactly the same rating for both experimental conditions (Table 4.5). This possibly indicates that the material and geometry difference of the insoles used did not contribute significantly to thermal perception over this short period of time.

Table 4.5. Thermal sensation ratings for the two conditions.

Condition	Participant number					
	1	2	3	4	5	6
Personalised	Warm	Slightly warm	Slightly warm	Warm	Slightly warm	Neutral
Control	Warm	Slightly warm	Slightly warm	Warm	Slightly warm	Neutral

With regard to running economy, the Student's *t*-test showed no significant differences between the two conditions for VO_2 consumption (25.762 mL/kg/min, ± 5.359 for the control condition and 26.379 mL/kg/min, ± 4.98 for the personalised condition). However, the laboratory could not be booked for 2 consecutive days, as recommended by Williams *et al.* (1991), so the physiology tests could not be duplicated to reduce within-subject variation, and it was not possible for participants to accommodate to the treadmill prior to the data collection session.

There was a trend for higher peak pressure under the heel and forefoot regions than the midfoot area for both conditions (Figure 4.12), The *t*-tests also revealed significant differences in pressure in the midfoot between the two conditions ($p \leq 0.01$), with the forefoot approaching significance (0 = 0.073). Interestingly, peak plantar pressure under the heel showed a greater difference (in comparison to the other regions) in mean values between the two conditions, but this was still not significant. This discrepancy can be explained by the fact that out of the 6 participants, only 4 demonstrated a reduction in mean pressure under the heel with the personalised insoles, whereas for the mid and forefoot pressures, the changes occurred in the same direction for all the participants.

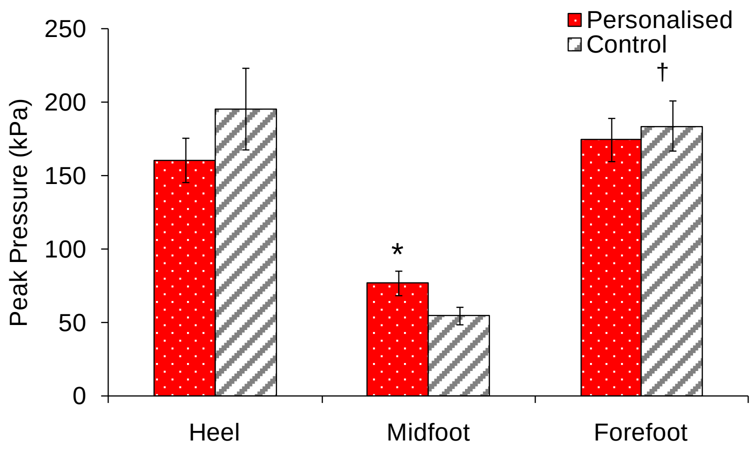


Figure 4.12. Peak mean pressure and standard deviation for the two conditions. (* $p \leq 0.01$; † $0.05 \leq p \leq 0.1$).

Analysis of the mean plantar contact area showed no significant differences between the two conditions (Figure 4.13).

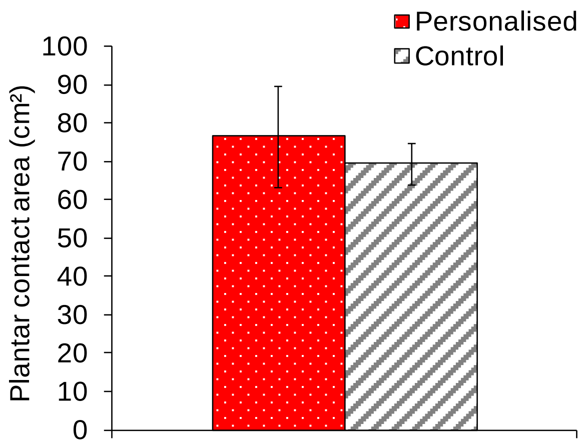


Figure 4.13. Mean plantar contact area and standard deviation for the two conditions.

The other biomechanical variables assessed were: rearfoot eversion, tibial internal rotation, and peak vertical impact. No statistical differences were found between the two conditions for rearfoot eversion and tibial internal rotation (Figure 4.14).

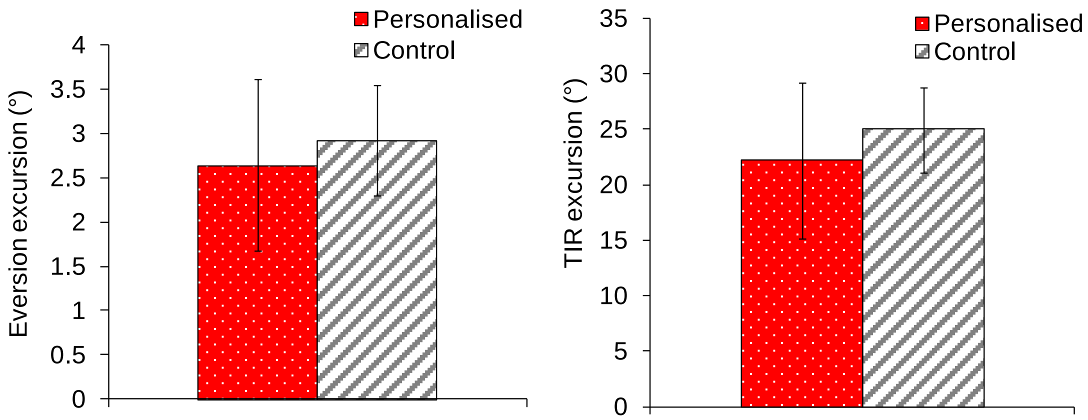


Figure 4.14. Mean angle and standard deviation for eversion excursion (left) and tibial internal rotation excursion (right).

Analysis of vertical impact peak force also showed no significant differences between conditions. Figure 4.15 displays the mean vertical ground reaction force over time for all participants and experimental conditions.

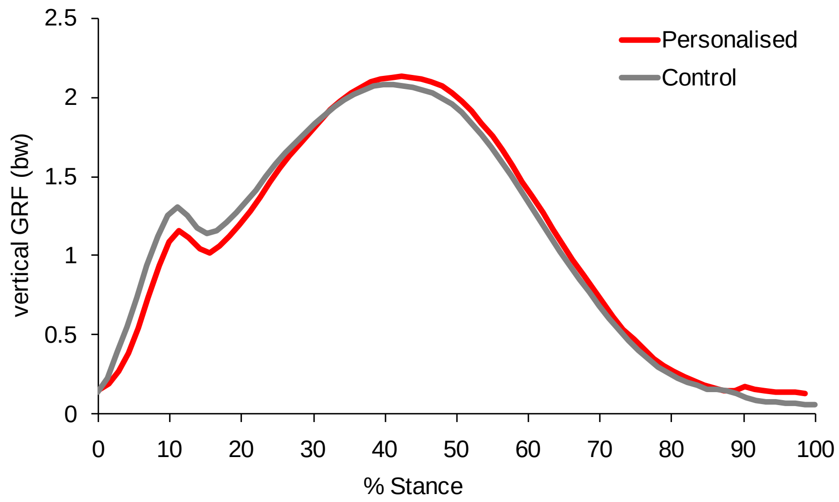


Figure 4.15. Mean vertical ground reaction forces for the personalised and control conditions.

Although there were no significant differences for most of the biomechanical variables, a trend can be observed from the data (Figures 4.12 and 4.14). Apart from midfoot pressure, all the variables analysed (heel and forefoot pressure, ankle eversion and tibial internal rotation and impact peak) showed reduced values for the personalised condition.

4.4.2. The personalisation process

It took approximately 25 minutes to take all 15 anthropometric measurements for each participant (Table 4.6), therefore ideally, this suite of measurements needs to be rationalised by identifying the most useful in designing and specifying the footwear. Table 4.7 displays the values of medial longitudinal arch, which was calculated to classify the arch structure of the individuals.

Table 4.6. Participants' anthropometric measurements (in millimetres).

Participant number	1	2	3	4	5	6
Foot length (1st digit)	246	259	272	217	255	221
Foot length (2nd digit)	235	256	265	212	241	219
Foot length (5th digit)	201	199	222	168	194	188
Metatarsale tibiale length	185	188	202	153	188	165
Metatarsale fibulare length	159	156	172	133	144	150
Foot breath	96	106	94	85	95	81
Heel breath	61	70	72	66	67	58
Dorsum height at 10%	63	68	67	49	64	51
Dorsum height at 90%	59	65	62	49	55	50
MPJ height	34	35	35	28	38	28
Hallux height	23	22	20	17	24	19
Navicular height	20	22	15	12	18	10
MPJ girth	237	258	239	204	250	198
Mid arch girth	229	253	251	206	238	191

Participant number	1	2	3	4	5	6
Heel girth	316	326	344	272	332	282

Table 4.7. Participants' medial longitudinal arch values.

Participant number	1	2	3	4	5	6
Relative arch deformation	1.120	0.675	0.806	0	2.072	0.344
Arch index	0.081	0.085	0.055	0.055	0.071	0.045
Arch ratio	0.341	0.362	0.332	0.320	0.340	0.309

From all the anthropometric measurements taken, only two, MPJH and hallux height, significantly correlated with the discomfort ratings. MPJH showed significant ($p \leq 0.05$) positive correlations with mean discomfort ratings in the midfoot ($r = 0.918$) for the control condition, and also with mean discomfort ratings in the forefoot ($r = 0.824$) and overall discomfort ($r = 0.872$) for the personalised condition. Hallux height showed positive correlation with discomfort ratings in the forefoot ($r = 0.896$) and overall discomfort ($r = 0.836$) for the personalised condition. No other significant correlations were found between anthropometric measurements and the discomfort, performance and biomechanical variables.

There were also no significant correlations between the discomfort and biomechanical variables and the arch ratio or arch index, but only participant 2 had a high arched foot while all the remaining 5 had a normally arched foot. Relative arch deformation showed significant positive correlations ($p \leq 0.05$) with mean discomfort ratings in the midfoot ($r = 0.910$ for the control and $r = 0.926$ for the personalised), in the arch ($r = 0.930$ for the control and $r = 0.906$ for the personalised), and for fit ($r = 0.757$ for the control and $r = 0.861$ for the personalised). RAD could help identify which individuals (i.e. those with stiff arches) could be predicted to report more discomfort with footwear.

The total time for the foot capture phase (3-D scanning and taking anthropometric measurements) was approximately 30 minutes, as shown in Table 4.8.

Table 4.8. Time required per individual to capture the foot.

Phase	Description	Time
1.	Positioning the foot to scan	4 minutes (both feet)
2.	Foot scanning	14 seconds (both feet)
3.	Identifying and marking of the anatomical landmarks	2 minutes
4.	Taking the anthropometric measurements described in Table 4.2	25 minutes
	Total	**31 min and 14 sec**

With regard to the design and manufacture of the personalised insoles, the point-cloud data generated from the scans proved to be noisy in terms of having a large amount unwanted or irrelevant data (Figure 4.16), giving the effect of a 'spiky' surface (Eggbeer, 2008) . This may be due to the number of lines per scan that was set for the scanner. Higher lines per scan would allow a better resolution, but it would also require additional seconds to scan, meaning that the participants could get fatigued in maintaining a static position for a prolonged time.

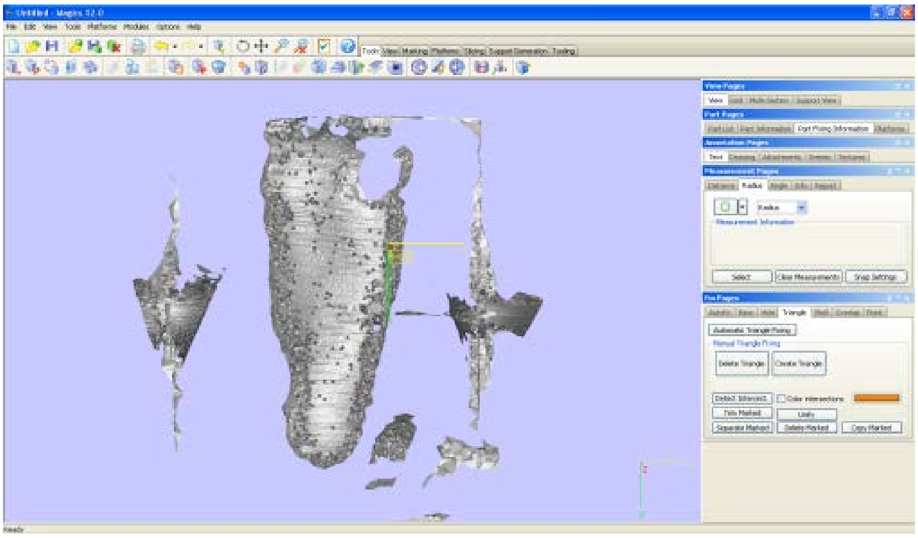


Figure 4.16. Screenshot of a raw triangulated data on Magics software.

The scan data were compatible with Magics software and, although this software enabled the additive manufacturing of parts (by allowing the design of fixtures, repairs, etc.), it did not provide all resources required for the design of the insoles, specifically for smoothing the jagged edges at the boundary of the data. The whole phase of insole design using the CAD software took two hours per pair (12 hours in total). Although this time appears excessive, the author had limited design experience, such that it is likely that this can be reduced.

The fabrication time for the insoles used in the trials was approximately 28 hours, as shown in Table 4.9. Nylon 12 (DuraForm® PA), the material used for the parts, demonstrated positive attributes: after the laboratory session with the runners, the personalised insoles were visually inspected and manipulated by hand, but showed no signs of breaking and cracking and all were in good condition. Also, the VAS and the thermal sensation scales suggested that there were no significant discomfort or thermal sensation wearing the insoles made from Nylon 12, when compared to the control condition.

Table 4.9. Approximated time required for the fabrication of the 12 insoles (6 pairs) using AM.

Phase	Description	Labour involved?	Approximate Time
1.	Preparation of the build set-up using Magics software.	Yes	30 minutes
2.	Machine set-up (powder and parameters).	Yes	30 minutes
3.	Machine warm-up time.	No	2 hours
4.	Build time (NB. all parts are built in one batch, not one after the other).	No	1 hour per part (12 hours in total)
5.	Machine cool down. Half of the time in the machine and half outside.	Yes, but only to move out the parts.	1 hour cooling per part (12 hours in total)
6.	Post-processing: 'cleaning up', removal of excessive power.	Yes	5 minutes per part (1 hour total)
	Total		**28 hours**

4.5. Discussion

This pilot study was conducted to develop, explore and refine the research methods and the process that delivers personalised insoles using AM. These will first be discussed in the context of the findings, followed by the limitations of the research and conclusions.

Discomfort ratings were low and no significant differences were found between the two experimental conditions. This suggests that the way the personalised 'glove fit' insoles were designed and manufactured neither reduced or caused significant discomfort in comparison with the original ones for a short period of running. The literature is more positive about personalised insoles. For example, Yung-Hui and Wei-Hsien (2005) showed that total contact inserts are effective in reducing discomfort when wearing high-heeled shoes and in runners, Mundermann *et al.* (2003b) reported that custom made orthotics presented more comfort in comparison to a control condition. Also, the fact that the thermal sensation was given the same rating for both conditions may indicate that the materials and geometry of the insoles used do not contribute significantly to the perceptions of thermal sensation after a short period of usage. The usefulness of the thermal sensation assessment should be questioned for short duration trials.

Although performance (as judged by running economy) did not show any significant differences between the two experimental conditions, these may not be reliable. Williams *et al.* (1991) reported that only with an average of 2 consecutive days of testing per individual can the RE values be reliable. For practical reasons the laboratory could not be booked for 2 consecutive days, therefore the performance tests were not duplicated to reduce within-subject variations, nor was there time for the individuals to accommodate to the treadmill. Although other studies could successfully evaluate the running economy wearing insoles (Hayes *et al*., 1983; Burton and Reilly, 1995), in the present study this test proved difficult to set up and book the laboratory for 2 days in order to get reliable data. Considering that a longitudinal study was planned for the next stage of the research, with a higher number of participants and sessions, the application of this test needed to be re-considered.

With regard the biomechanical variables, peak pressure in the midfoot area was significantly greater in the personalised condition compared to the control. On the other hand, the peak pressure in the forefoot region was approaching significance ($p = 0.073$), with the personalised condition showing reduced values. The results indicate a trend that the type of insoles designed and manufactured in the present study can be beneficial by redistributing the plantar pressure from areas with a higher peak (i.e. heel and forefoot) to the other areas with lower plantar pressure values (i.e. midfoot). The results are in agreement with the literature. Chen *et al.* (2003) documented that total contact inserts significantly reduced plantar pressure in the metatarsal and heel regions and redistributed pressure to the midfoot area, in comparison to a flat insert. Likewise, the total contact inserts utilised by Yung-Hui and Wei-Hsien (2005) reduced peak pressure in the heel and medial forefoot regions, but increased pressure under the midfoot area.

It was anticipated that areas with high peak pressures would have more reported discomfort (Hennig *et al*., 1996; Jordan *et al*., 1997; Yung-Hui and Wei-Hsien, 2005). However, in this study there were no significant differences in the mean discomfort ratings for the midfoot region between the two conditions. This could be due to the type of activity the participants were asked to perform. They only ran for 6 minutes before rating each condition; it is possible that differences become more evident over time and once individuals become fatigued. Also, according to Chen *et al.* (1994), plantar pressure distribution is more associated with comfort in walking than running.

Orthotics are reported to reduce of the degree of rearfoot eversion in comparison to a non-orthotic insert (Rodgers and Leveau, 1982; McCulloch *et al*., 1993). In addition, those that provide arch support, similar to the ones employed in the current research, are described as being efficient in making individuals walk in a more ‘natural manner’ by reducing the degree of rearfoot eversion (Nakajima *et al*., 2009). However, this could not be confirmed by the results of the current study. Also, the literature reports positive correlations between arch stiffness and tibial rotation (Nigg *et al*., 1998) and that individuals with stiff arches are thought to be poor shock absorbers in comparison to people with flexible feet (Butler *et al*., 2007), which would influence the impact peak values. However, perhaps as expected due to the small sample size, this was not the case in this pilot study, although there was a trend for lower values for the personalised condition for all the kinematic and GRF data. This probably can also be explained by the fact that the active peak values were on average 2 times body weight, which may correspond to slow running, as in the literature the active peak is typically 2.5-3 body weight in running (Rodgers, 1988). Furthermore, the insoles were developed to be a glove fit as the research was aimed at developing personalised insoles that would be available for a wider number of individuals. The correction of the foot or gait requires expertise and the researcher would always advocate that individuals seek specialist help, increasing the complexity of the personalisation process and cost of footwear. As reported earlier, the foot position was discussed with 3 podiatrists and they suggested that the dynamic scanning would be the ideal way of capturing the foot, but this not being possible, the non-weight bearing foot scan would be best option. They also indicated that the arch support and heel cup design of such insoles could provide benefits in terms of reducing the injury risk.

In general, the personalisation process showed promise in terms of the scan data, with the entire foot capture taking approximately 30 minutes (Table 4.8). The data files were also suitable and compatible throughout the process with the hardware and software utilised, although they had a large amount of noise. The noise in the scan data refers to the points that deviate from the object surface (the foot in this case) and can affect the quality of the data (Bibb, 2006). In this pilot study, the scanner utilised had only one camera, so it provided just a plantar image of the foot, which would not be suitable for the design of the entire shoe. The foot was captured in a non-weight bearing position to suit the scanner and positioning each foot took on average 2 minutes. The actual foot scanning took only 7 seconds per foot (14 seconds in total), but the literature is inconsistent when reporting scanning time. Payne (2007) estimated 1 minute for foot scanning, whereas Zhang *et al.* (2010) reported only 20 seconds to capture the surface of the whole body. This discrepancy can be due to a number of reasons. Although neither Payne (2007) nor Zhang *et al.* (2010) mentioned the type of scanner used, scanning time can be dependent on number of cameras, resolution and type of scanner (e.g. light, laser) recruited, among other factors. Also, Payne (2007) rounded the estimation times to the nearest minute, meaning that the 1 minute reported could be less.

Although the foot position adopted may not be considered ‘gold standard’, the insoles did not cause significant discomfort in comparison to the original ones. As mentioned in Chapter 3, the ideal foot scan should be done dynamically, so that the insoles manufactured would take into account the significant changes in shape during the ground contact. There are new scanners that capture a maximum of 46 frames per second (Schmeltzpfenning *et al*., 2010), allowing the generation of point cloud data for the different phases of ground contact. However, these systems are still expensive and exclusive and their application to footwear design remains unknown.

One of the objectives of this pilot study was to rationalise the suite of anthropometric measurements by identifying the most useful in designing and specifying personalised footwear. It is therefore of interest that from the 15 anthropometric measurements taken, only five (MPJ and hallux height, length from the heel to the 1st and 5th MPJs, and RAD) proved to be directly useful for specifying the design of the insoles. For example, the measurements from the heel to the 1st and 5th MPJs were important in the design of the insoles by identifying their end points. This suggests that the time required to take these measurements (25 minutes) could be reduced substantially. The study from Hawes and Sovak (1994), which consisted of a sample of 1197 Caucasian North American male subjects, reported that 22 anthropometric measurements of the foot were taken in approximately 5 minutes, suggesting that the measuring time could be reduced significantly with practice. However, more evidence is needed to either confirm or reject this. As mentioned in Chapter 3, the extraction of the foot dimensions can potentially be done electronically from the scan data, but the scanner used in this study did not allow whole-foot capture.

With regard to the design of the personalised insoles, the point-cloud data generated from the scans were compatible with the Magics software. Nevertheless, even though this software enabled the additive manufacturing of parts (by allowing the creation of triangles, repairs, etc.), it did not provide all of the features required for the design of the insoles, especially for smoothing the surface and evening out the jagged edges on the boundaries of the data. Because this feature is not available in Magics, the insoles had to be sanded manually by the researcher to ensure all the sharp edges were removed from the insoles. The author acknowledges that the Magics software is primarily for STL repair and build set-up, but it was the only software available to this research at the time. As mentioned earlier, it is possible that FreeForm (SensAble Technologies, Inc., USA), Geomagic Studio (Geomagic Inc., USA) or Magics CAD

(Materialise Group, Belgium) programs used in other studies for reverse engineering can provide a more complex range of resources and thus be more appropriated for this type of data manipulation (Bibb *et al*., 2006; Tuck *et al*., 2008; Sun *et al*., 2009; Pallari *et al*., 2010). No literature was found comparing different computer software for reverse engineering. The studies of Bibb *et al.* (2006), Tuck *et al.* (2008), Sun *et al.* (2009) and Pallari *et al.* (2010) did not mention any labelling of their parts, but for personalisation this would be essential to facilitate matching the insoles with the respective person. If this process is applied to a larger scale, ways of identifying the parts quickly and easily is an important consideration. This need acknowledged by Bibb (2006), who stated that embossing patient names, orientation markers or handles could be added to drilling guides for oseeointegrated implants if necessary

The whole phase of insole design using CAD software took approximately two hours per pair (12 hours in total). Tuck *et al.* (2008) reported that the data manipulation phase of customised aircrew seat manufacture takes approximately 20% of the entire process, whereas in the present study, the same operation took approximately 30%. On top of the laser sintering (LS) costs (which includes a technician), the data manipulation phase requires a CAD specialist to design the insoles or footwear for manufacture, making this possibly the most expensive part of the process. In a similar process to the one described, Pallari *et al.* (2010) included a clinical evaluation by a podiatrist in order to mass customise orthoses for rheumatoid arthritis suffers using AM. The research was presented in detail, but no explanation was given on how much time and cost the podiatrist would add or how they would determine whether to use weight-bearing or non-weightbearing foot scans.

The fabrication time for the insoles used in the trials was 28 hours (Table 4.9). In this case, customers would have to order the insoles or footwear and pick them up after a few days, similar to when ordering glasses from an Optician. Although the current study did not attempt to evaluate the cost to produce the insoles, approximately £50 a pair has been estimated by Saleh and Dalgarno (2010) to produce foot orthoses using LS. According to Hague *et al.* (2003b), the costs of manufacturing using AM are guided by the time required to build a given volume of parts, which in turn is established by the orientation that the component is built in. Also, the parts costs depend on filling available machine capacity for each given build session (i.e. machine utilisation, volume, etc.). Nevertheless, accurate costing will be subject to commercial development at a later stage, thus not addressed in this thesis.

4.5.1. Limitations

The main limitation regarding evaluation of the insoles themselves is the sample size in comparison to other studies. This must be considered as a possible explanation for the lack of significant differences between the two experimental conditions. Also, individuals only ran for six minutes before rating each condition in terms of discomfort. It is possible that differences in self-reported discomfort can only be observed when individuals become more fatigued.

The difference in materials between the two experimental conditions could have influenced the discomfort and biomechanical data: the personalised used Nylon 12 whereas the original insole of the control was made from foam. Current evidence suggests that insole materials are linked to an individual's perceived sensations and muscular activation (Nigg *et al*., 2003; Witana *et al*., 2009). Table 4.10 summarises the limitations of the current study that require modification in the methodology for further research within this thesis.

Table 4.10. Limitations of the pilot study and proposed alternative for further research.

Limitation	Limitation	Proposed alternative
Running economy	Tests could not be duplicated to reduce within-subject variations. No time to accommodate participants to the treadmill prior to the data collection session.	To remove the performance tests as part of the footwear evaluation, given that the next study will measure a high number of participants in multiple laboratory sessions.
Magics software	The software did not provide all the resources required for manipulating the scan data, because it is primarily for STL repair and build set-up.	To investigate the use of Geomagic Studio, Magics CAD or FreeForm software instead.
Insole material	The personalised insole used Nylon 12, whereas the control was the shoes' original, made from foam.	To have a control insole made from the same material, stiffness and size (three-quarter) as the personalised.

In addition, limitations in the scanner had an effect on the foot position captured, but this method was discussed with podiatrists prior to the start of the pilot and there is no consensus in the literature with regard to the optimal scan and foot position. Besides, the glove fit insoles produced from the scan of the plantar surface of the feet did not increase discomfort reported or affect the performance or biomechanics of the lower extremities in comparison to the control condition. As mentioned in Section 3.2.1.1 (Chapter 3), the ideal foot scan should be done dynamically, so that the insoles manufactured would take into account the significant changes in shape during the ground contact, but this type of scanner is still expensive and not widely available commercially.

4.6. Conclusions

From the pilot study conducted, it is possible to identify the pros and cons of the personalisation process for insoles at this stage.

1) The glove fit personalised insoles showed similar discomfort ratings in comparison to the original ones for 6 minutes of use.
2) The glove fit personalised insoles appear to redistribute the plantar pressure by reducing the high peaks from the heel and forefoot areas and increasing pressure in the midfoot.
3) The foot capture phase (3-D foot scanning and taking anthropometric measurements) of the personalisation process took approximately 30 minutes in total per individual.
4) Two anthropometric measurements, foot length from the heel to the 1st and 5th metatarsophalangeal joints, showed potential in designing the glove fit personalised insoles by indicating their end points. Relative arch deformation, metatarsophalangeal joint height and hallux height correlated with the discomfort ratings, indicating that these dimensions may help to determine which individuals may have more discomfort with footwear.
5) The design of the insoles (i.e. cleaning the point cloud data, smoothing, thickening and converting into an STL file) using the Magics software took 2 hours per pair, but this time is expected to be reduced with practice.
6) An approximate time of 28 hours was taken to fabricate 12 parts, from the preparation of the build set-up until the post-processing (removal of excessive power). The visual inspection and physical manipulation of the insoles indicated that the material (Nylon 12) showed good durability (no signs of breakings or cracking were noted).

The main limitations of the study and the personalisation process were.

1) The running economy test proved to be difficult to conduct due to the number of sessions required to obtain reliability. Hence, performance could not be measured reliably.
2) The Magics software is not the ideal tool for the design of the personalised insoles, because it is primarily for STL repair and build set-up. Other software (e.g. Geomagic Studio, Magics CAD or FreeForm) needs investigation.
3) Although some suggestions have been made in this pilot study, the ideal foot scanning position and anthropometric measurements needed to specify the insoles are still unclear as they have not been explored enough.

4) The effects of longer use of the personalised insoles on the discomfort and biomechanical parameters need further exploration.

The footwear personalisation process described and explored in this pilot study shows potential and can be considered a good starting point for this research. The scan data files were compatible with all hardware and software utilised throughout the process, indicating that manufacturing personalised insoles via foot scans and AM is feasible. Furthermore, the personalised insoles designed and manufactured did not cause significant discomfort or change the biomechanical variables in comparison to the original ones. However, further research is needed to investigate the short and medium term use of personalised insoles in terms of discomfort and biomechanics.

Chapter 5: The short and medium term evaluation of personalised footwear: a longitudinal study

5.1. Introduction

The previous chapter reported on a pilot study that explored the proposed personalisation process and the ways of evaluating footwear in terms of discomfort, performance and lower extremity biomechanical variables. The findings indicated that manufacturing insoles via reverse engineering and additive manufacturing (AM) is feasible, but that further search is needed on the short and medium term use of such footwear. Short, medium and long terms are not clearly defined in the literature and they mainly depend on the product. In case of running trainers, their life cycle is usually between 480-800 km depending on the usage, which corresponds to an average of 36-59 weeks (Runner's World, 2001; New Balance, 2011). Therefore, for the purposes of this study, short term is defined as the period up to 1 month, as this is long enough to gather initial impressions with the shoes. Medium term can be considered between 1 and 12 months as this can provide further adjustments of the individual with the footwear. Long term is the period over 12 months, because this allows the deeper adaptations (e.g. running injuries) to be detected.

There are many studies that evaluate the short term use of the use of insoles or orthotics in terms of comfort and biomechanics, such as Chen *et al.* (1994) and Yung-Hui and Wei-Hsien (2005). However, according to MacLean *et al.* (2008), data from such studies are usually collected at the time of dispense (short term intervention), but a question that often arises is whether there are further adaptations that occur with a prescribed period of wear (medium and long term). Therefore, evaluating a longer period of use of personalised footwear can provide useful information regarding the any adaptations that can occur over time in the discomfort perception and biomechanical parameters.

5.2. Aim and objectives

The main aim of the study reported in this chapter was to evaluate the short and medium term use of personalised insoles in terms of discomfort and biomechanical variables of the lower extremities (Objective 2). Another objective set out in Section 1.3 (Chapter 1) was also explored further:

- to refine the process that delivers personalised footwear using additive manufacturing (Objective 1).

5.3. Research method

5.3.1. Study design and rationale

This thesis' focus is to develop and explore footwear personalisation using AM and to evaluate such footwear in terms of comfort and health. Once the methods and techniques had been tested and initially explored in the pilot study, a longitudinal study was conducted.

Based on time and costs constraints, it was decided that the longitudinal study would follow-up runners for a 3-month period, a time period considered by the researcher as sufficient to understand the effects of the short and medium term use of the personalised insoles. However, unlike the pilot study, it became evident that there would be difficulties using a repeated measures design, as the participants would have to be involved in the experiment for 6 months. This long term investigation could be problematic not only in maintaining the runners committed, but also in keeping reasonable the total period required to conduct the study. Therefore, a matched pairs design was utilised, given that the independent groups design requires more participants taking part to ensure that each group is similar and representative of the population targeted (Fallowfield *et al*., 2005). Therefore, participants were paired according to: age, gender, body mass index (BMI) and kilometres ran per week and were randomly allocated to one of the two experimental conditions: control and personalised. Each experimental condition is detailed in Section 5.3.3.2. Like in the pilot study, a single-blind experimental design was utilised to minimise any undesirable attitudes by the participants that could be prejudicial to the results of the study.

From the methods explored in the pilot study, there were two main changes in equipment. First, the scanner used in the pilot was on loan from Pro-Fit Technologies, so it had to be returned after a period of 3 weeks. Thus, a new scanner was bought, which was mounted by the manufacturer (3D Digital Corporation) to scan the whole foot and allow a more comfortable foot position, as requested by the 'Elite to High Street' research team. This laser scanner consisted of 4 independent cameras (model: RealScan USB 200; 3D Digital Corporation, Newtown, USA), all with the same specification which were positioned surrounding a glass plate, where the foot was placed. Therefore, the whole foot scanner was in fact 4 scanners (cameras) that operated sequentially. Appendix 5.1 details the cameras' specifications and Figure 5.1 shows the whole scanner, with the dimensions and location of the cameras identified; 2 of the cameras are in the box to capture the bottom view of the foot. The cameras were independent, but the final data combining the 4 scans was generated by the scanner's software, allowing whole foot capture.

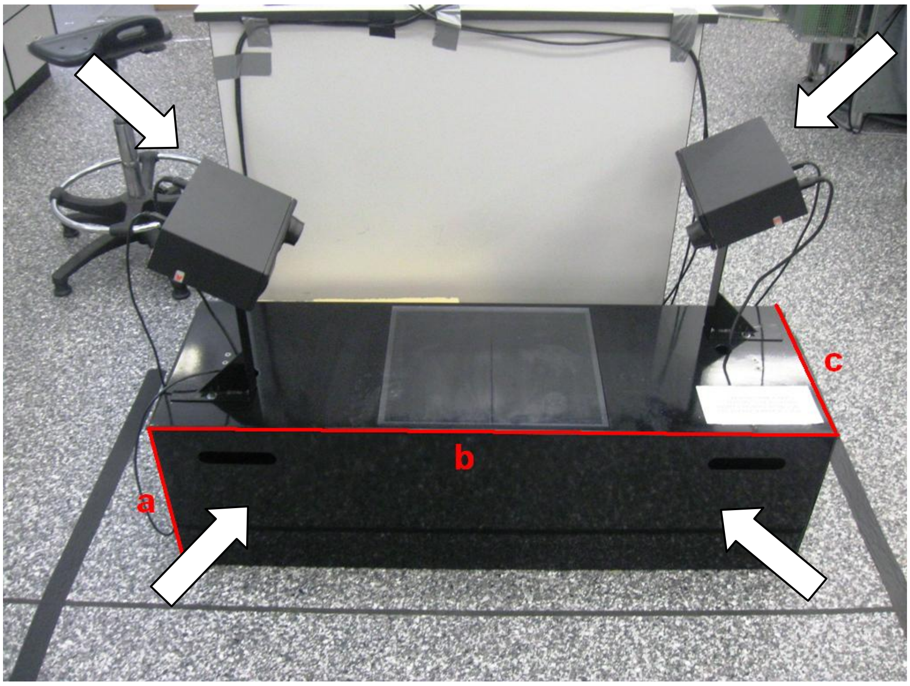


Figure 5.1. The 4-camera three-dimensional laser scanner used in the study. Measurements are: a = 36 cm; b = 120 cm; c = 40 cm. The arrows identify the location of the cameras.

The second alteration refers to the reverse engineering software used to manipulate the scan data. Once the Magics software proved to be improper for data manipulation and insole design in the pilot study, a Geomagic Studio (version: 10; Geomagic, Inc, Durham, USA) was then used in this study. This software was chosen because it was recommended by the Additive Manufacturing Research Group at Loughborough University, which had used it for similar applications, and a license would incur no extra cost.

In addition to these alterations, the researcher developed an Activity Diary to allow participants to document, after every training session with the footwear, the date, length of the run, level of physical activity and any discomfort felt. For the information on the level of physical activity, pedometers were supplied (Clemes and Parker, 2009). A visual analog scale (VAS), similar to the one used in the pilot study, was added to the Activity Diary, so the participants could report any discomfort felt during a particular training session with the shoes. The Activity Diaries were discussed during the laboratory sessions mainly to understand any problems with its completion and/or the trainers. They also enabled any differences between groups in terms of usage of the trainers during the 3 months to be identified. Section 5.3.3.3 will provide more information about the Activity Diary and pedometer used.

5.3.2. Sampling strategy

In order to help determine the minimum sample size, a power analysis calculation was carried out. Plantar pressure and overall discomfort data from the pilot study were used in the power analysis. To achieve a significance level of 5% and minimal statistical power of 90%, the sample size required ranged from 9 (using heel pressure data) to 727 (using overall discomfort data). With such a large variation in the recommended sample size, it was decided that a minimum of 12 matched pairs would be required, based on previous studies that have evaluated the use of insoles/footwear in terms of comfort and biomechanics (e.g. Yung-Hui and Wei-Hsien, 2005; MacLean *et al*., 2008). Anticipating that some participants may discontinue the study because of the time commitment required, the aim was then to recruit 32 individuals (16 pairs: 8 male pairings and 8 female pairings). Inclusion criteria were as described for the pilot study:

- 18 to 65 years old;
- run at least 5 kilometres per week;
- have no reported musculoskeletal symptoms or injury in the last 12 months;
- have not used an orthosis in the last 12 months.

Ethical approval was issued on 30 April 2009 by the Ethical Advisory Committee from Loughborough University under the Ref No: R09-P64. The sample was recruited adopting a stratified random sampling strategy to obtain a broad range of individuals. The population was stratified in terms of age (18-30, 31-42, 43-54 and 55-65), BMI (under weight, normal weight and over weight) and kilometres ran per week (5-10, 11-20, 21-35 and 35+). The aim was that at least one matched pair with each characteristic was recruited. For recruitment, posters (Appendix 5.2) were placed in gyms and leisure centres in Loughborough, and buildings in the university. Running clubs around the Loughborough area were also contacted either in person or by e-mail. Snowballing techniques, such as word of mouth were also used in the search for participants.

5.3.3. Study procedure

The first contact with interested individuals was made via e-mail, telephone or face to face, when a brief explanation of the 'Elite to High Street' project and the nature of the study were given. Following this, a participant information sheet, similar to the one developed for the pilot, but modified in relation to the details of the longitudinal study, was given (Appendix 5.3). If the individual was still keen to take part, the researcher asked his/her body mass, height, gender, km covered per week and trainers' size and was then told that they would need to wait until another runner with similar characteristics was recruited. Individuals that were selected for the study were asked to attend 4 laboratory sessions over approximately 16 weeks. The same New Balance trainers (model: NB-757, Neutral Cushion) used in the pilot were used and two conditions, control (shoe + control insole) and personalised (shoe + personalised 'glove fit' insole), were compared through single blind trials over the 3-month period. The participants were informed that this research would form part of a bigger project (Elite to High Street) that aims to develop personalised sports footwear, but no detail was disclosed with regard to the trainers provided in the study nor that a control condition would be used.

5.3.3.1. Session 1: foot capture

On arrival, the study was explained in detail to the participants, emphasising the long term commitment required. A physical activity and health screen questionnaire, similar to the one used in the pilot, was completed (Appendix 5.4). If the individual was suitable to take part, a consent form was given, including gaining permission to record them using Vicon System, scan their feet, and informing them that they may discontinue the study at any time, without having to give any reason for doing so (Appendix 5.5).

Also during the first session, detailed anthropometric measurements of the right foot were taken, following Hawes and Sovak (1994) and Williams and McClay (2000). The methodology of taking the measurements was the same as the one described in Chapter 4 (Table 4.2; Figure 4.3): 15 anthropometric measurements, with participants standing on a block with their feet shoulder width apart (Figure 4.2); and from these measurements, arch ratio, arch index and relative arch deformation (RAD) were calculated (see Section 4.3.2.1, Chapter 4).

Finally, the individuals' feet were scanned, using the 4-camera three-dimensional laser scanner described previously; the scanner consisted of 4 independent cameras all with the same specification. Scans were taken with participants sitting on a chair, lightly resting their foot on the glass of the scanner (at 10% of weight bearing), maintaining 90° at the ankle joint and the lower leg perpendicular to the glass of the scanner (Figure 5.2). In order to ensure that the participants applied approximately 10% of the weight bearing during the scans, a weight scale was placed on the glass of the scanner for their practice and then removed for the scan. The 10% of load on the foot was chosen because the scanner used would require the foot to be placed on the glass and because it would be difficult to apply no load to the foot, even though evidences show that most of the changes to the foot shape occur with 10% of the weight bearing (Houston *et al*., 2006).

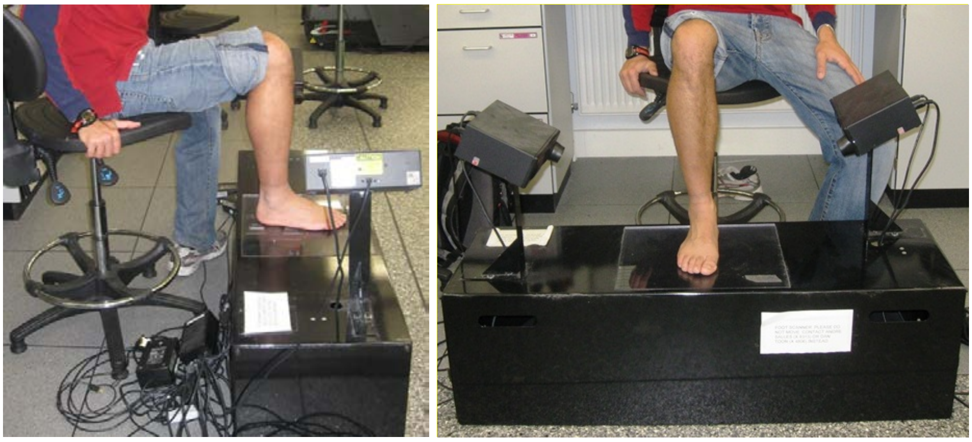


Figure 5.2. Side (left) and front (right) views of a participant having the foot scanned, maintaining 90° at the ankle joint and the lower leg perpendicular to the scanner.

The scanner was configured to capture 500 lines per scan (which can be set between 200 – 1000 lines) for two main reasons. Firstly (and unlike the pilot study), participants could rest their foot on the scanner, so the higher number of lines possible was selected to allow a better resolution. Secondly, the cameras operated one at the time, starting in sequence (e.g. camera 1 started at 0 seconds, camera 2 at 15 seconds, camera 3 at 30 seconds and camera 4 at 45 seconds). Configured to scan 500 lines, each camera would take 15 seconds for each scan. Thus, although the scanner could work with up to 1000 lines, a higher number of lines would make the laser beams overlap, affecting the quality of the data.

5.3.3.2. Experimental conditions

To construct the personalised insole, the foot scan data taken during the first session were opened in the Geomagic Studio software (version: 10; Geomagic, Inc, Durham, USA) and manipulated to rectify and delete unwanted data, but preserving as much as possible of the original geometric accuracy. The scans were also electronically engraved to a depth of 0.5 mm to help the identification of parts. More specifically, the data were 'cleaned' to remove the unwanted 'noise', smoothed, thickened to 2 mm, engraved with the participant number and converted into a stereolithography (STL) file. Because this scanner allowed a whole foot capture, a height of 15 mm for the heel cup was stipulated based on the trainers' original insoles, which had similar height in the heel region. Unlike this study, in the pilot it was not necessary to stipulate the heel cup height as the scanner only provided a plantar view of the foot. The insole design is detailed in Appendix 5.6.

The thickness of the insoles was changed in comparison to the pilot study because using the Geomagic Studio software, 2 mm offered a similar stiffness to the insoles developed for the pilot study, which had 3 mm thickness. Because the 2 mm thickness made them quite rigid, the insoles provided heel cup and arch support, but not correction of lower limb abnormalities. Therefore, the personalised condition consisted of the New Balance trainers fitted with personalised 'glove fit' insoles that were designed and manufactured from the scans of the participants' feet to match the exact plantar geometry their feet from the heel to the base of the metatarsal heads. The parts were manufactured from Nylon 12 (DuraForm PA®), using laser sintering (LS), an AM process (Figure 5.3). An example of the personalised insole is shown in Figure 5.4.

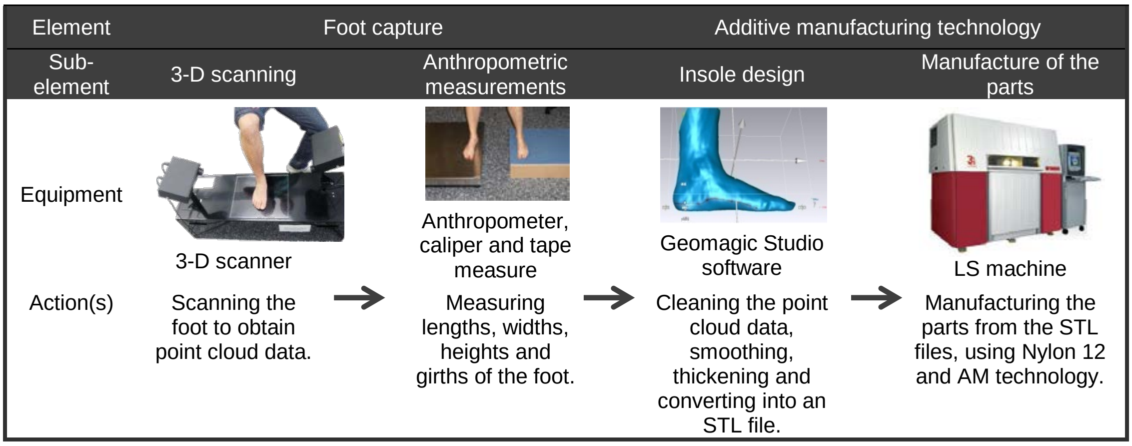


Figure 5.3. Flow chart showing the insole personalisation process explored in the longitudinal study.

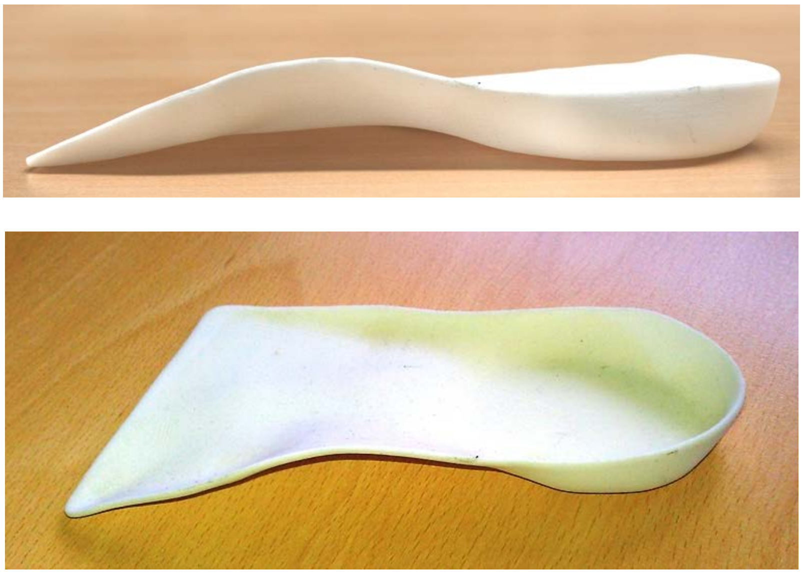


Figure 5.4. Medial (top) and top-medial (bottom) views of a personalised insole.

From the pilot study, it could have been the insole material that affected the discomfort and the biomechanical data, therefore the control condition consisted of the same trainers, but fitted with a pair of insoles that were manufactured from the scans of the original New Balance insoles, but using the same material and thickness as the personalised condition. The only difference was that the control insole was decreased by 2 mm (i.e. modified to be a 2 mm smaller in every direction, creating an additional polygon surface) in order to accommodate the 2 mm thickness. The process of control insole design is described in Appendix 5.7. Thus, the control condition had identical shape as the trainers' original insole, but was manufactured using AM to have same thickness (2 mm), stiffness and material (Nylon 12) as the personalised insole (Figure 5.5).

Figure 5.5. The original insole (left) and the control condition (right) used in the study.

After the parts were manufactured, the same microporous polyurethane foam used in the pilot was used to cover both insoles (Figure 5.6) to ensure a blind trial and provide extra comfort. It was also checked that the insoles would fit inside of the trainers properly. Hence, the only difference between the two conditions was their geometry: one was a personalised ‘glove fit’ insole (personalised) and the other was a generic shape based on the original insole (control).

Figure 5.6. Top view of the foam used to cover both experimental conditions.

5.3.3.3. Session 2: footwear evaluation (month 0)

The second session took place approximately 3 weeks after the first. It was used to introduce the participants to the trainers, Activity Diary and pedometer; reinforce the study's procedures, and to collect the discomfort (VAS) and biomechanical data (plantar pressure, vertical GRF, knee and ankle kinematics).

At the start of the second laboratory session, participants were fitted with a pair of New Balance shoes, with either a personalised or a control shape insole (randomly assigned to one of each pair). Since it is well established in the literature the linear increase of the vertical ground reaction force with increasing running speed (Nigg *et al*., 1987), electronic timing gates (model: SmartSpeed; Fusion Sport, Brisbane, Australia) were positioned in the middle of a 10-meter runway (Figure 5.7) to minimise the possible effects of the running velocity in the parameters measured. The double beam configuration for the timing gates was chosen as it has been shown to reduce the root mean square errors in comparison to a single beam (Yeadon *et al*., 1999). A speed of 2.78 m/s (± 5%) was established for the trials to ensure that all individuals (with different levels of training) included in the study could run naturally. Therefore, before collecting the biomechanical data, participants had 5 practice trials to run for 10 meters in order to familiarise themselves with the required speed.

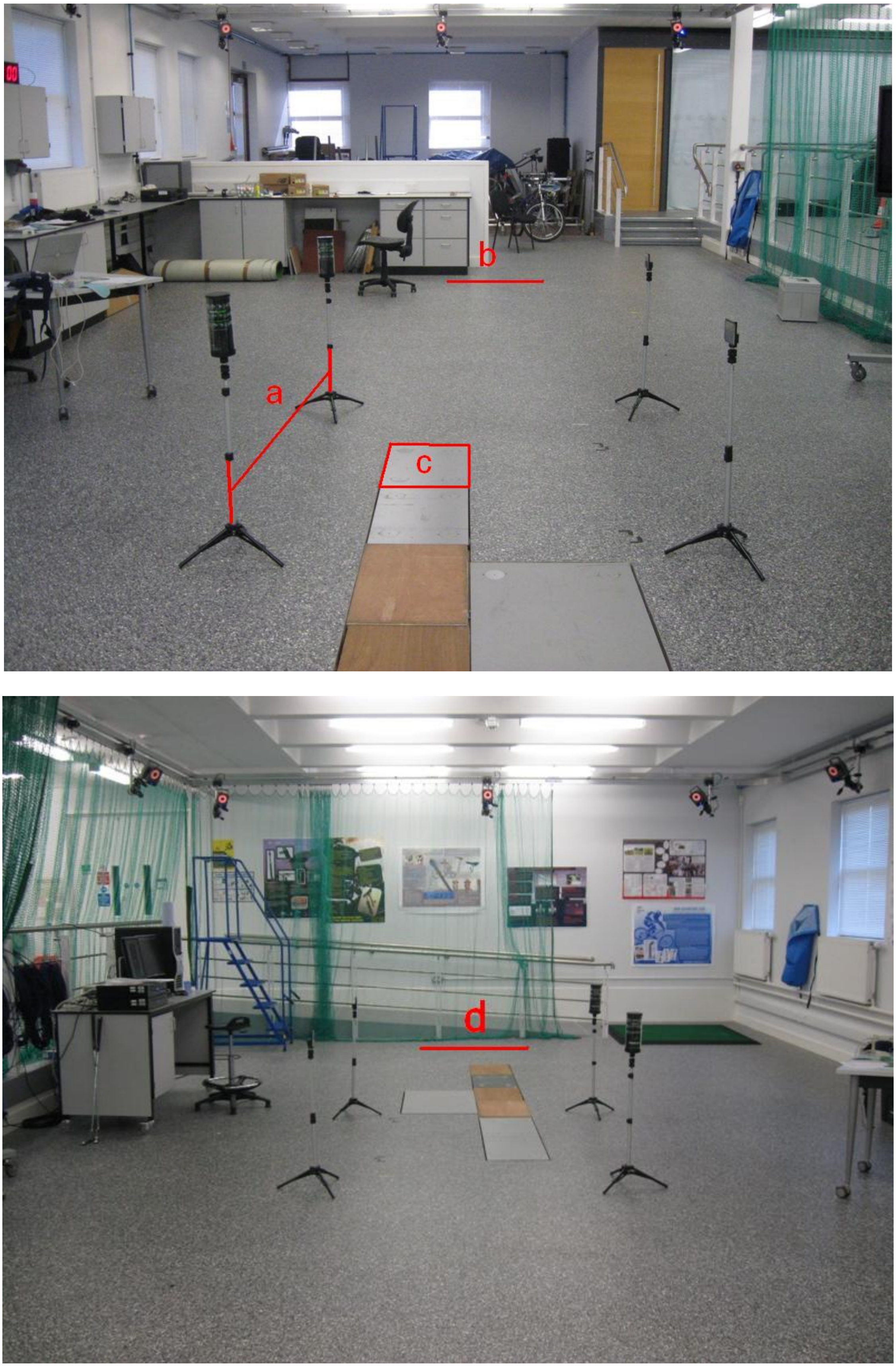


Figure 5.7. Views of the laboratory set up with the 10-m runway, electronic timing gates and Vicon system; (a: 2-metres distance between timing gates; b: start of the runway; c: the force platform used in the study; and d: end of runway).

After the practice trials, the F-Scan Mobile (Tekscan Inc, South Boston, MA, USA) in-shoe plantar pressure distribution sensor (N/cm^2) was placed inside the shoe to measure plantar pressure distribution recording at 250Hz (see Chapter 4 for more details). The participants then ran 5 times under the same experimental condition for 10 meters (Figure 5.8).

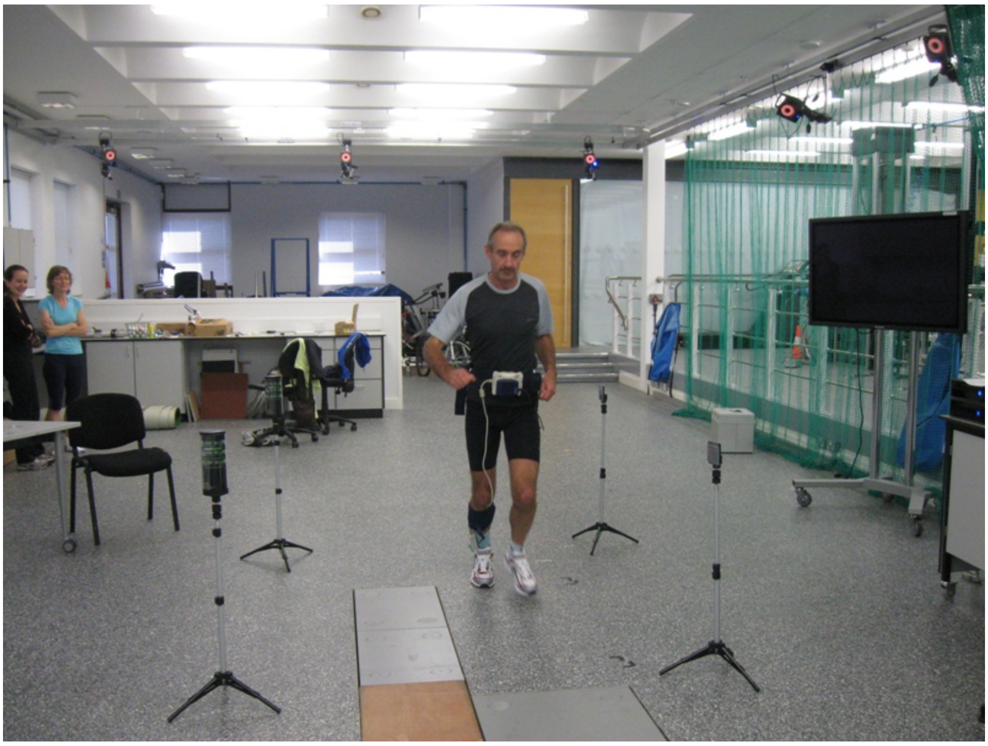


Figure 5.8. Participant running whilst his plantar pressure is recorded.

After 5 valid trials were recorded (i.e. speed was within the range accepted), the pressure sensor was removed from the shoe and 16 reflective markers (14 mm diameter) for tracking 3-D movement were placed according to the Plug-in-Gait (PiG) standard lower body modelling (Figure 5.9). See Chapter 4 for the exact marker placement and Appendix 5.8 for how the PiG calculates the joint centres and angles. Participants were then asked to run 5 times while the 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: 9281CA; Kistler Instrumente AG, Winterhur, Switzerland) was synchronised with the kinematic data. For all biomechanical data collected, the trials were accepted only if the speed was 2.78 m/s (± 5%). For the kinematics and ground reaction force (GRF) data, the trials were accepted if the right foot contacted the force platform entirely and no obvious alteration of the running pattern was noticed by the researcher.

Figure 5.9. Front and back views of a participant with the reflective markers attached. See Chapter 4 for a detailed marker placement.

The biomechanical data of the participants were also recorded running with the original New Balance insole, repeating the same protocol described above. This was necessary to provide a baseline within individuals and normalise the data, allowing a direct comparison between the matched pairs of individuals. Therefore, it was only in the second session of the study that participants were recorded twice (with the original and experimental insoles).

After the biomechanical data were collected, participants were given the same 150 mm visual analog scale (VAS) as used in the pilot study to measure perceived discomfort (Appendix 5.9). Once again, six aspects of the shoe were covered: overall, forefoot, midfoot, heel, arch and fit. At the end of the second session, participants were given the pair of New Balance trainers, fitted with a personalised or a control insole, the Activity Diary and a pedometer (model: NL-800; New-Lifestyles Inc, Lee's Summit, USA) (Figure 5.10). The pedometer provided information about their level of physical activity during the monitoring period (usage of the trainers). This model of pedometer was chosen as it is considered as "a highly accurate research-grade pedometer, suitable for use across all BMI groups" (Clemes *et al*., 2010).

Figure 5.10. Activity Diary, pedometer and trainers fitted with the insoles.

The participants were then informed to wear the trainers and the pedometer every time they went jogging/running for a 3-month period as well as complete the Activity Diary (Appendix 5.10) after each training session. In addition, the appropriate position to wear the pedometer was shown to the participants, but this was also described in the Diary. In the Diary, they were asked to note the date, the start time, estimate the length of the run, steps taken (from pedometer) and any discomfort felt. The participants were instructed that, if they felt any discomfort during the training session, they should rate it on the same 150 mm VAS used in the laboratory sessions, marking only the scale(s) that corresponded to the discomfort (e.g. forefoot) and leaving the others blank. To help with the understanding of the potential reason(s) for the discomfort, they were also asked to comment on what could be the cause(s). The Diary was returned and discussed with the researcher in laboratory sessions 3 and 4.

Participants were also told to only wear the running shoes provided for jogging/running and were encouraged to contact the investigator at any time if they had any concerns, problems or if they rated discomfort as 'not comfortable at all' for any aspect of the shoe in the Activity Diary. The data collected in session 2 is referred to as 'month 0' when reporting the findings from this study.

5.3.3.4. Session 3: footwear evaluation (month 1.5)

The third session took place approximately 1.5 months after the second session (month 0). On arrival, the researcher inspected the trainers, insoles and the foam material that covered the insoles visually and manipulated them with his hands in the search for any signs of wear and cracking. Also, the author reviewed the Activity Diary to make sure it was being completed as instructed and to de-brief on any discomfort reported. In sequence, all the material (trainers, insoles, pedometer and Activity Diary) was discussed with the participants. The researcher was mainly interested on their impressions (fit, discomfort) about the shoes and insoles, and if they had any difficulty in working with the Diary and pedometer. The completed sheets of the Activity Diary were collected and further ones were provided if necessary. Discomfort and biomechanical data were then collected following the protocol described for session 2 (month 0). The data collected in session 3 is referred to as 'month 1.5' when reporting the findings from this study.

5.3.3.5. Session 4: footwear evaluation (month 3)

The fourth and last session took place approximately 1.5 months after the third session (month 1.5). The protocol was the same as described for month 1.5, i.e.: examination and discussion about the trainers, insoles and Activity Diary, and the collection of the discomfort and biomechanical data. At the end of session 4, the pair of New Balance shoes used in the experiment (with the original insole) was given to the participants to thank them for their time. The data collected in session 4 is referred to as ‘month 3’ when reporting the findings from this study. Table 5.1 summarises the laboratory sessions and the primary data collected in each one.

Table 5.1. Laboratory session schedule for the participants.

Lab session – Month	Data collected
Session 1 – Introduction	Anthropometric measurements and scans of the foot
Session 2 – Month 0	Discomfort and biomechanics
Session 3 – Month 1.5	Activity Diary, discomfort, biomechanics and visual inspection of the material.
Session 4 – Month 3	Activity Diary, discomfort, biomechanics and visual inspection of the material.

5.4. Data analysis

The data from this study was treated and analysed in a similar way to the pilot, as explained in Chapter 4. The personalisation process was evaluated mainly through the discomfort and biomechanical data (Chapter 4, Section 4.3.2). For the purpose of the analysis of the plantar pressure data, the foot was divided into three regions: heel, midfoot and forefoot (Chapter 4, Section 4.3.3). Peak mean pressure was measured in each region using F-Scan Mobile Research software (version: 5.72; Tekscan Inc., USA) and provided information about the highest mean pressures under the foot during the ground contact. Values for mean contact area were obtained using the same F-Scan software.

The biomechanical data collected with the Vicon System and force plate were extracted using the software Vicon Nexus (version 1.5.2; Vicon Motion Systems, Oxford, UK). The kinematic data of the knee and ankle analysed are listed in Table 5.2. To assess these variables, the same definitions as for the pilot study (Chapter 4, Section 4.3.3) were made, but, in addition, the knee and ankle joints’ maximum angles were also assessed, which were defined as the joints’ highest angle recorded during ground contact.

Table 5.2. Definition of the kinematic parameters analysed in the study. See Appendix 5.8 to understand how PiG calculates the joint centres and angles.

Parameter	Definition
Knee flexion at FS	**Knee flexion:** the sagittal plane of motion of the knee.
Maximum knee flexion	
Knee abduction at FS	**Knee abduction:** the frontal plane of motion of the knee.
Maximum knee abduction	
Knee internal rotation at FS	**Knee internal rotation:** the transverse plane of motion of the knee.
Maximum knee internal rotation	
Ankle dorsiflexion at FS	**Ankle dorsiflexion:** the sagittal plane of motion of the ankle.
Maximum ankle dorsiflexion	
Ankle eversion excursion	**Ankle eversion:** the frontal plane of motion of the ankle.
Maximum ankle eversion	
Tibial internal rotation (TIR) excursion	**TIR:** the internal rotation of the tibia, with respect to the foot. The transverse plane of motion of the ankle, since the rearfoot was considered fixed on the ground for the majority of the stance.
Maximum TIR	

The vertical GRF variables analysed were: mean loading rate, impact peak and active peak. Mean loading rate was calculated as the rate of rise of the impact peak over its interval period of 20% to 80%. This interval period was chosen because it is the most linear portion of the loading curve (Milner *et al*., 2006). Impact peak was defined as the first peak, whereas active peak was defined as second peak in the vertical GRF data (Figure 5.11).

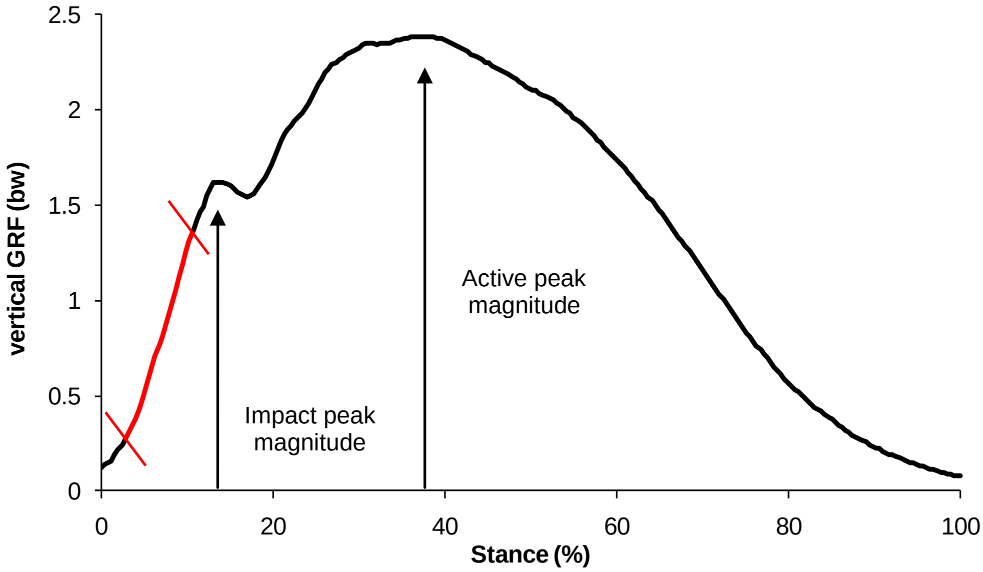


Figure 5.11. Example of a vertical GRF showing how the loading rate (in red, with the 20% and 80% moments identified), impact peak and active peak were identified.

The biomechanical variables (knee and ankle kinematics, GRF and plantar pressure) were all normalised within individuals according to the original insole data taken in session 2 (month 0) of the study. For the kinematic data, the original insole was set as 'zero' and any increase or reduction in angle was computed. The plantar pressure and GRF data were calculated as increases or reductions in percentages. Participants were not paired according to their biomechanical characteristics, therefore not normalising the data could indicate that any differences between conditions could be due to natural discrepancies in gait pattern between paired individuals, rather than the effect of the insoles *per se*. Thus, normalisation would allow a true comparison of the effects of the insoles on gait characteristics.

A *two-way* (2 x 3) repeated measures analysis of variance (ANOVA) was used to test for the significant main effects of the experimental conditions (personalised and control) and sessions (months 0, 1.5 and 3) and the interactions between these. As this study was a matched pairs design, this type of ANOVA test was suitable as two factors were repeated (condition and session). If a significant main effect was found for session, a post hoc test using a Bonferroni correction for multiple comparisons was applied to determine which pairwise comparisons were different. The Mauchly's test of sphericity was carried out to check for violation of the ANOVA assumption and the Greenhouse-Geisser method was used to correct for cases of non-sphericity. The pattern of data distribution was also visually checked for normality. A *one-way* ANOVA was performed to detect significant differences within groups in the discomfort data because there was only one factor (the session). The level of significance was chosen as $p \leq 0.05$ and Statistical Package for the Social Sciences (SPSS) software for Windows (Release 17.0, SPSS©, Inc., 2008) was used for all statistical analyses.

As mentioned earlier, the personalisation process was evaluated as in the pilot study (Chapter 4, Section 4.3.2). For example, Pearson's product moment correlation coefficient was used to detect relationships between the 15 anthropometric measurements taken and the dependant variables, which were: discomfort ratings, plantar pressure distribution, knee and ankle kinematics and GRF. Initially, statistical analyses were conducted to detect relationships between the anthropometric measurements and the discomfort and biomechanical data taken in session 2 (month 0) of the study. If significant correlations were found, further analyses were carried out for months 1.5 and 3. Also, the additive manufacturing technology phase was evaluated with regard to the time to design the insoles, usefulness of the software (Geomagic Studio) and durability of the material (Nylon 12) (see Chapter 4 further details).

A paired samples Student's *t*-test was used to detect significant differences between the two conditions (personalised and control) for the Activity Diary variables: length of the runs, steps taken and discomfort ratings. The length of the runs and steps taken were analysed as mean minutes or steps per week (12 weeks = 3 months) (Clemes and Parker, 2009). If a participant did not use the trainers in a particular week, he/she was attributed ‘zero’ minutes for that week. The discomfort data was analysed as mean discomfort ratings per half of the monitoring period: first (0 – 1.5 months) and second half (1.5 – 3 months). If the participant did not report any discomfort in a training session, the discomfort rating was considered as ‘zero’ (the most comfortable condition imaginable). Finally, the reasons the participants reported for the discomfort were organised and listed as percentages of total causes in first and second halves of the study.

5.5. Results

In total, 80 recreational runners showed an interest in taking part in the research and, from these, 65 met the selection criteria. Data collection took place over a 14 month period, starting in June 2009 and finishing in August 2010. The objective was to recruit 16 pairings (32 individuals), but during the course of the study, 7 participants (3 from the control group and 4 from the personalised group) discontinued, leaving the study with only 10 complete pairs. Therefore, the author decided to recruit 3 extra pairings (6 runners), increasing the total sample size to 38 runners. First, this section will report on the entire data of the 13 pairings that completed the study, followed by the results of the other participants (7 participants that discontinued and the remaining 5 unpaired individuals).

The 13 pairings of participants that completed the study had an age range of 19-53 years. Table 5.3 displays their characteristics. As expected, as they were paired according to age, gender, BMI and km ran per week, the *t*-tests indicated no significant differences between the groups.

Table 5.3. Characteristics of study participants. Data shown as mean (SD).

Condition	Personalised (n=13)	Control (n=13)	p value
Age (yrs)	32.8 (9.7)	34.5 (11.1)	0.101
Height (cm)	171.8 (7.1)	168.7 (6.6)	0.206
Body mass (kg)	68.5 (13.8)	68.7 (12)	0.935
BMI	24.1 (3.6)	23 (3.3)	0.208
Shoe size range (UK)	5-11	3.5-11	0.833
Running per week (km)[1]	13.2 (7.4)	14.6 (8.3)	0.154
Gender	6M and 7F	6M and 7F	

[1] ‘Running per week’ means the amount of running the participants reported in the health screen questionnaire at the start of the study for the purpose of matching pairs.

5.5.1. *Discomfort*

The discomfort ratings taken in the laboratory sessions were generally low for both experimental conditions throughout the 3 months (Figure 5.12). Statistical analysis revealed significant main effects for the variable ‘session’ for overall discomfort ($p \leq 0.01$). The post hoc tests indicated that these differences were between month 0 and month 1.5 ($p \leq 0.01$) and months 0 and 3 ($p \leq 0.05$). Significant main effects for ‘session’ were also found for arch discomfort ($p \leq 0.05$), while the post hoc analysis indicated that the significant differences were only between months 0 and 3 ($p \leq 0.05$), although the differences between months 0 and 1.5 were approaching significance ($p = 0.70$). All these discomfort variables were significantly reduced over time (i.e. month 0 > month 1.5 > month 3). The ANOVA also indicated significant main effects of the condition for the heel ($p \leq 0.05$) and fit ($p \leq 0.05$), while the forefoot ($p = 0.078$) and midfoot ($p = 0.056$) were approaching significance, whereby the ratings were lower for the personalised condition. Finally, there were significant ‘session’ by ‘condition’ interaction for the forefoot ($p \leq 0.05$) and approaching significance for fit ($p = 0.056$) discomfort. There were no significant ($p > 0.05$) main effects for the session, the condition or interactions between the two (session and condition) for the remaining aspects of the shoe.

A trend in the data was observed, that all of the mean discomfort ratings from the laboratory sessions were lower for the personalised condition in comparison to the control for the 3 month period. These data are compatible with the qualitative notes taken by the researcher during the laboratory sessions, which documented that most of the participants reported experiencing comfort under the heel region wearing the personalised condition. It seems that the heel cup design of the personalised insoles gave them the sensation of the foot being stabilised and of a good fit. On the other hand, the participants felt the arch design of both insoles (personalised and control) were ‘intrusive’ and too rigid, which can explain the higher ratings of discomfort in this area.

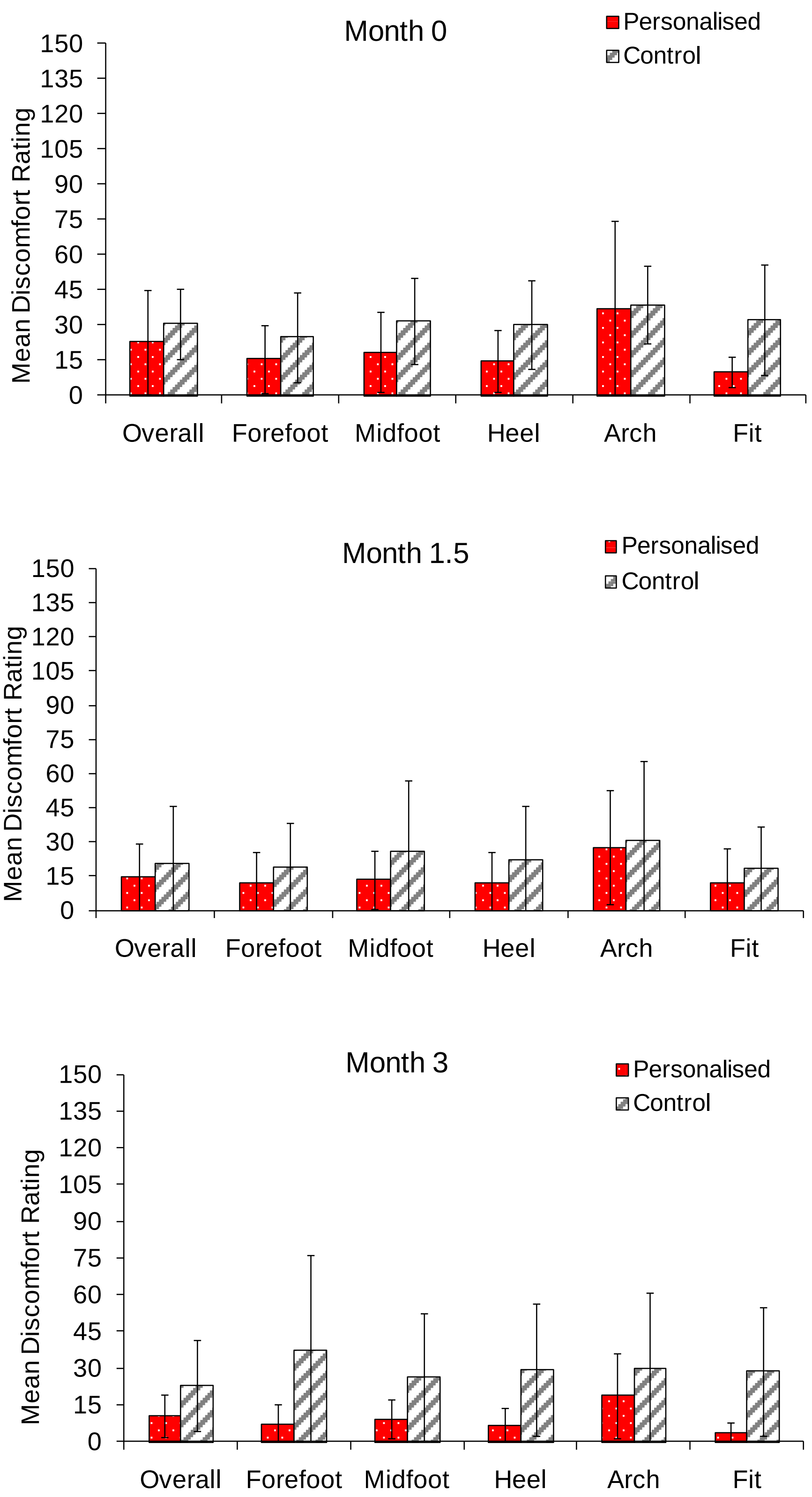


Figure 5.12. Mean discomfort ratings and standard deviation for the personalised and control conditions in months 0, 1.5 and 3. The graphs follow the VAS, which was 150 mm long, with both ends labelled (0 – 'most comfortable condition' to 150 – 'not comfortable at all').

In order to further explore discomfort, the data were also analysed within conditions to investigate differences between laboratory sessions. Figure 5.13 indicates that the discomfort ratings reduced in each session for the personalised condition. Significant differences were found for the following aspects: overall discomfort between months 0 and 3 ($p \leq 0.05$), forefoot between months 1.5 and 3 ($p \leq 0.05$), heel between months 0 and 3 ($p \leq 0.05$) and 1.5 and 3 ($p \leq 0.05$), arch between months 0 and 3 ($p \leq 0.05$), and fit between months 0 and 3 ($p \leq 0.01$) and 1.5 and 3 ($p \leq 0.05$). In addition, other variables were approaching significance: overall between months 0 and 1.5 ($p = 0.096$), forefoot between months 1 and 3 ($p = 0.053$), and arch between months 0 and 1.5 ($p = 0.073$).

With regard to the control condition (Figure 5.13), the pattern seems to be that there was a reduction in discomfort ratings from month 0 to month 1.5, then an increase for all aspects analysed from month 1.5 to 3. Statistical analysis showed a significant difference for overall discomfort between months 1.5 and 3 ($p \leq 0.05$) and forefoot discomfort between months 0 and 3 ($p \leq 0.05$) and months 1.5 and 3 ($p \leq 0.05$). Overall discomfort was also approaching significance between months 0 and 3 ($p = 0.064$).

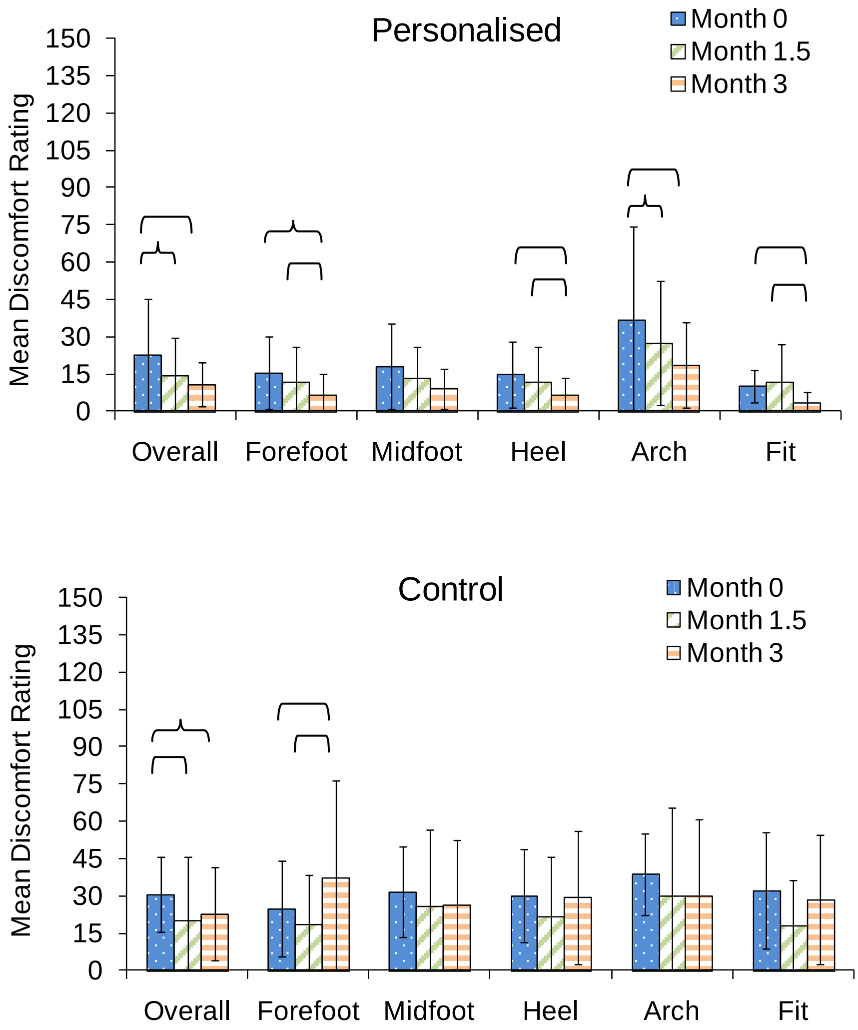


Figure 5.13. Mean discomfort ratings and standard deviation within the personalised and control conditions in months 0, 1.5 and 3. = $p \leq 0.05$; = $0.05 \leq p \leq 0.1$

5.5.2. *Activity Diary*

The Activity Diary supported the discomfort ratings taken during the laboratory based sessions. Participants were instructed to report any discomfort (in any region of the body), during their running sessions when using the trainers supplied for them. Figure 5.14 shows the mean weekly use of the trainers by the participants in terms of the steps taken and minutes of use. Although the control sample took slightly more steps overall, statistical analysis indicated no significant differences between conditions ($p > 0.05$) for their weekly running duration or the number of steps taken.

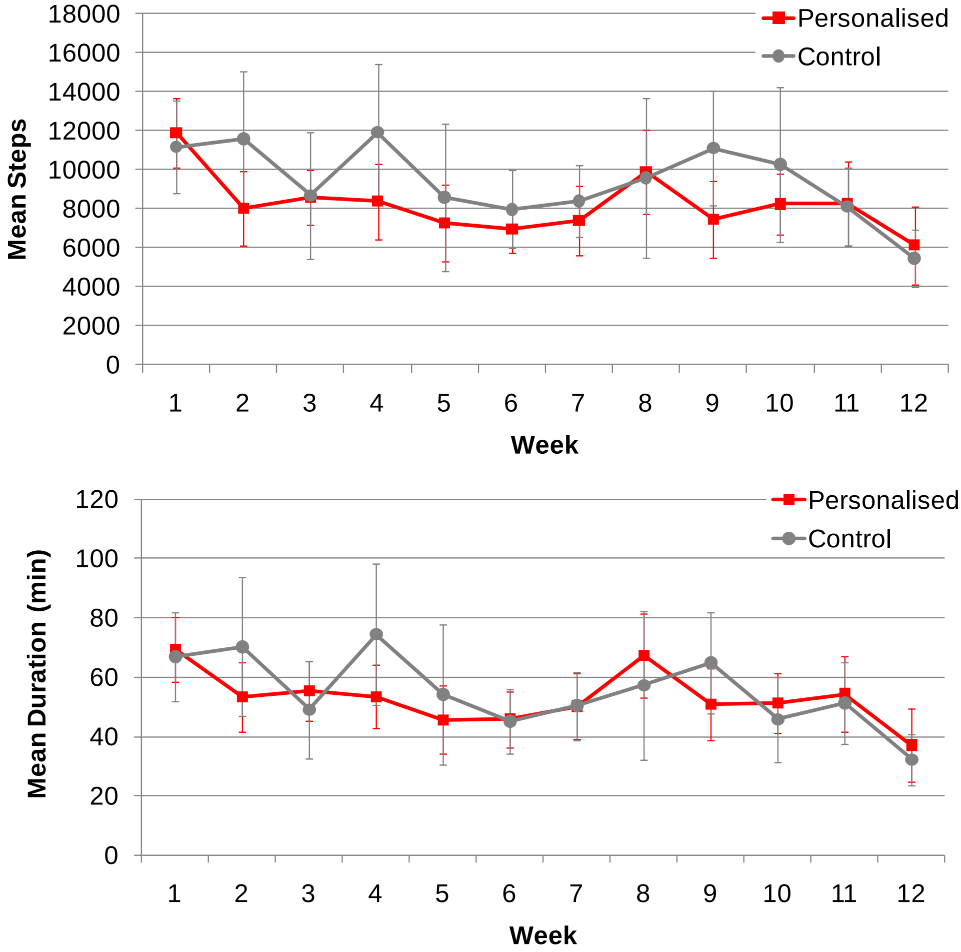
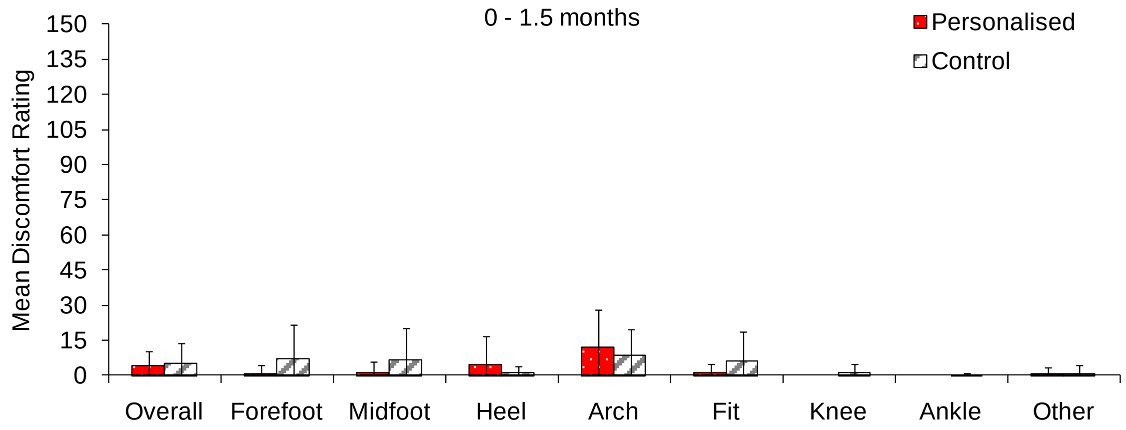


Figure 5.14. Mean weekly usage of the trainers and standard error in terms of step count (top) and duration (bottom) over the 3-month (12-week) period. No significant differences were found between conditions for both mean steps and duration.

During the first months of usage of the shoes (0 – 1.5 months), participants from both conditions reported low mean discomfort ratings in the Activity Diaries (Figure 5.15). The arch had most reported discomfort for both conditions, similar to that reported during the laboratory sessions. In later months (1.5 – 3 months), these participants reported less discomfort during their training sessions, but the arch region had higher ratings. Interestingly, there were no significant differences between conditions for all the discomfort ratings reported in Figure 5.15. It is also intriguing to note that the mean discomfort ratings of the training sessions were overall considerably lower than the ones reported in the laboratory sessions, as can be seen clearly in Figure 5.15.



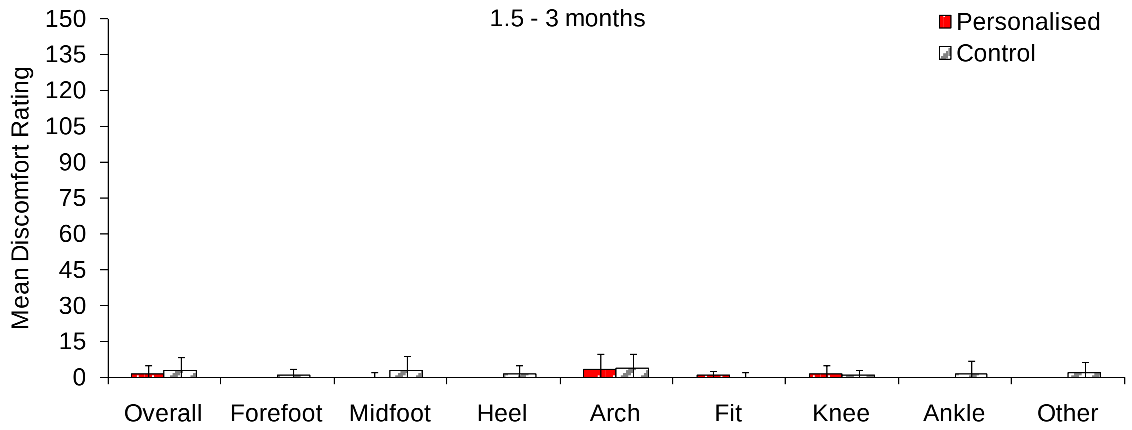
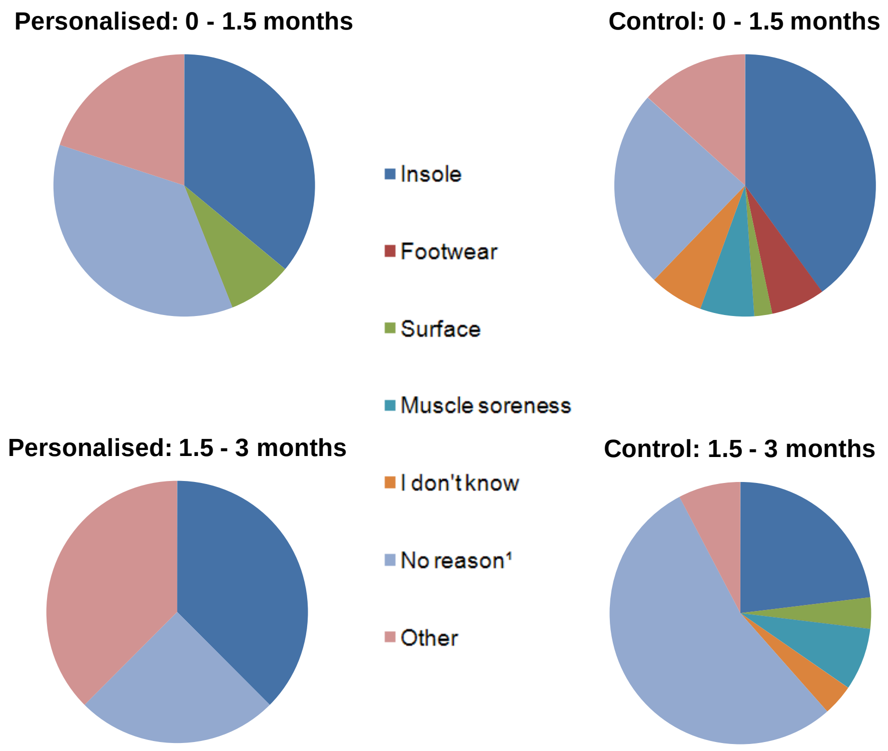


Figure 5.15. Mean discomfort ratings and standard deviation reported in the Activity Diary for the personalised and control conditions over the first (0 – 1.5) and second (1.5 – 3) halves of the study.

Figure 5.16 shows the reasons reported by participants in the Activity Diary to have attributed to the discomfort felt during the training sessions. Among the causes, the insoles themselves were the most frequently mentioned component for both conditions: in the personalised, they accounted for 35% in first (0 - 1.5 months) and 38% in second half (1.5 - 3 months), whereas in the control, they were mentioned 40% and 24% of the time in the first and second halves of the study respectively. However, in many cases, the participants did not suggest a source for the discomfort i.e. they did not complete part v of the Activity Diary. More specifically, in 35% of the cases in the first (0 – 1.5 months) and 25% of the cases in the later months (1.5 – 3 months) of the study, the runners in the personalised condition did not mention a cause for their discomfort. In the control condition, these values were 40% and 54% in the first and later months respectively. It is likely that, when the cause was not documented, the participants did not have time to do so, as they were asked to report ‘I don’t know’ when the cause for the discomfort was unknown.



[1] "no reason" means that the participant did not attribute a reason for their discomfort (i.e. part v of the Diary was not completed).

Figure 5.16. Reported causes of discomfort in the Activity Diary during the first (0 – 1.5) and second (1.5 – 3) halves of the study.

5.5.3. Biomechanics

In general, changes in the biomechanical data collected over the 3 laboratory sessions were less systematic than the discomfort ratings, and no clear patterns were found. However, a trend was noted that changes in the biomechanical variables occurred mainly in the impact phase, i.e. between 0 and 20% of ground contact, when the body is absorbing shock from the ground. This section will first approach the kinematic data of the ankle and knee, followed by the vertical GRF and the plantar pressure analysis.

Statistical analysis of the ankle (Figure 5.17) indicated significant main effects of the 'session' for ankle eversion excursion ($p \leq 0.05$), with post hoc analysis indicating an increase over time, which was approaching significance between months 0 and 1.5 ($p = 0.63$) and months 1.5 and 3 ($p = 0.77$). Significant main effects of the session number were also detected for maximum tibial internal rotation (TIR) ($p \leq 0.01$). Post hoc analysis showed that differences were between months 0 and 1.5 ($p \leq 0.05$) and months 0 and 3 ($p \leq 0.01$), with month 0 showing reduced values. Finally, significant main effects for 'session' for TIR excursion ($p \leq 0.001$) were detected and post hoc analysis indicated that the differences were between months 0 and 1.5 ($p \leq 0.05$) and months 0 and 3 ($p \leq 0.01$). Significant main effects of the experimental condition were only found for ankle dorsiflexion at foot strike ($p \leq 0.05$) and maximum ankle eversion ($p \leq 0.05$). No significant differences were found between the session number and experimental condition for the other variables ($p > 0.05$) and no significant 'session' by 'condition' interaction was detected for any of the variables.

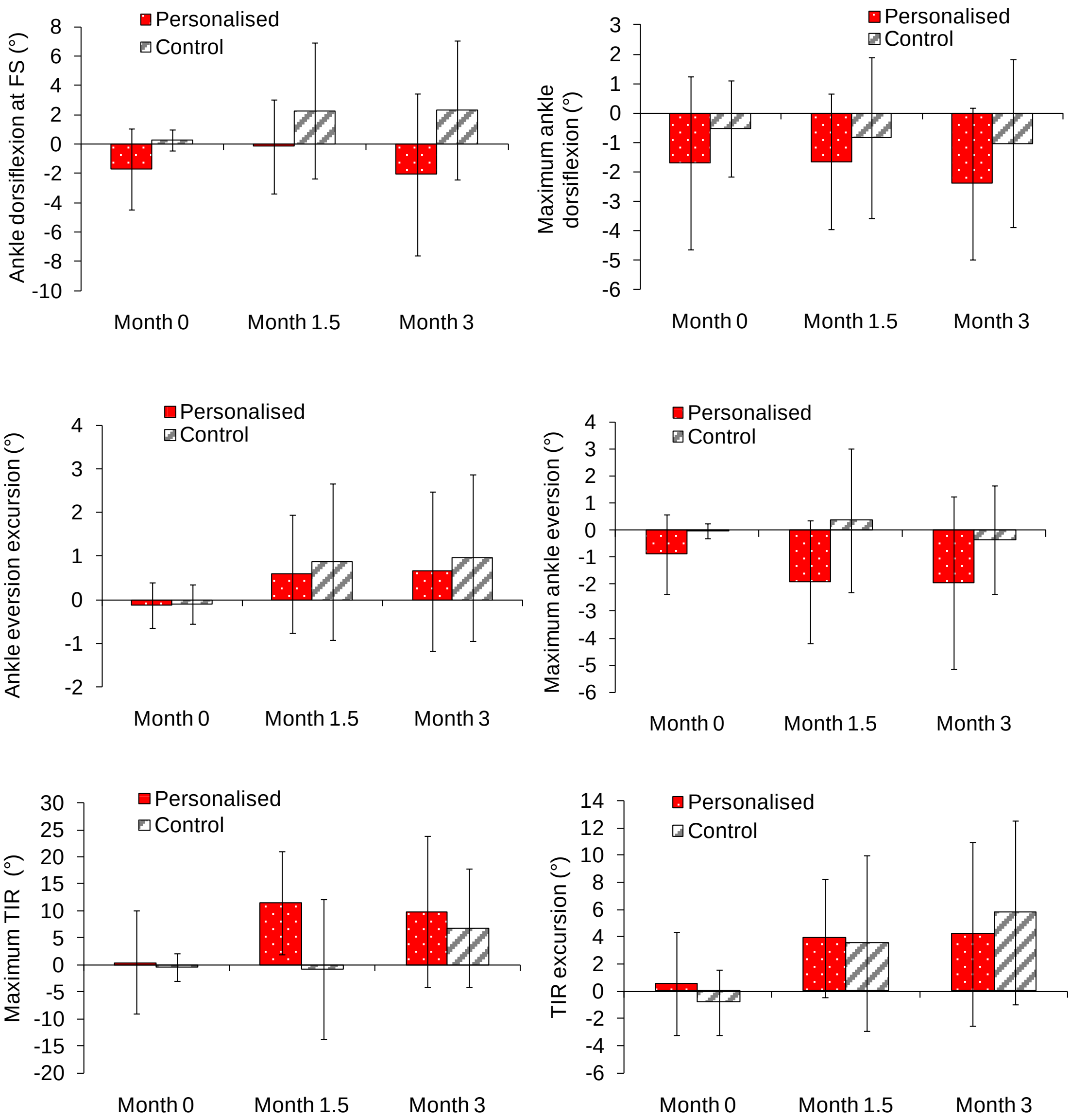


Figure 5.17. Ankle kinematic parameters. FS: foot strike; TIR: tibial internal rotation. NB: data is normalised within individuals: positive values indicate increases and negative values reductions compared to the original insole data.

Statistical analysis of knee kinematics (Figure 5.18) showed significant main effects of the session number for knee flexion at FS ($p \leq 0.01$), with post hoc analysis indicating that differences were between months 0 and 3 ($p \leq 0.001$), while months 0 and 1.5 were approaching significance ($p = 0.055$), with month 0 showing lower values when compared to months 1.5 and 3. Also, significant effects for 'session' for maximum knee flexion ($p \leq 0.001$) were found. Post hoc analysis showed that significant differences were between months 0 and 3 ($p \leq 0.001$) and months 1.5 and 3 ($p \leq 0.05$), with month 3 showing higher values when compared to the other two. In addition, significant main effects of the session number for maximum knee abduction were observed ($p \leq 0.05$), but post hoc analysis has indicated that these differences were only between months 0 and 3 ($p \leq 0.05$) with month 3 showing reduced values. Significant effects of the 'session' number for knee internal rotation at foot strike had higher values for session 3 ($p \leq 0.05$). However, the post hoc analysis has indicated that the differences were only between months 0 and 3 ($p \leq 0.05$). Finally, significant main effects of the experimental condition were found only for knee internal rotation at foot strike ($p \leq 0.05$), with the personalised condition presenting significantly reduced values. There were no significant main effects of the 'session', experimental condition or 'session' by 'condition' interaction for any of the other variables.

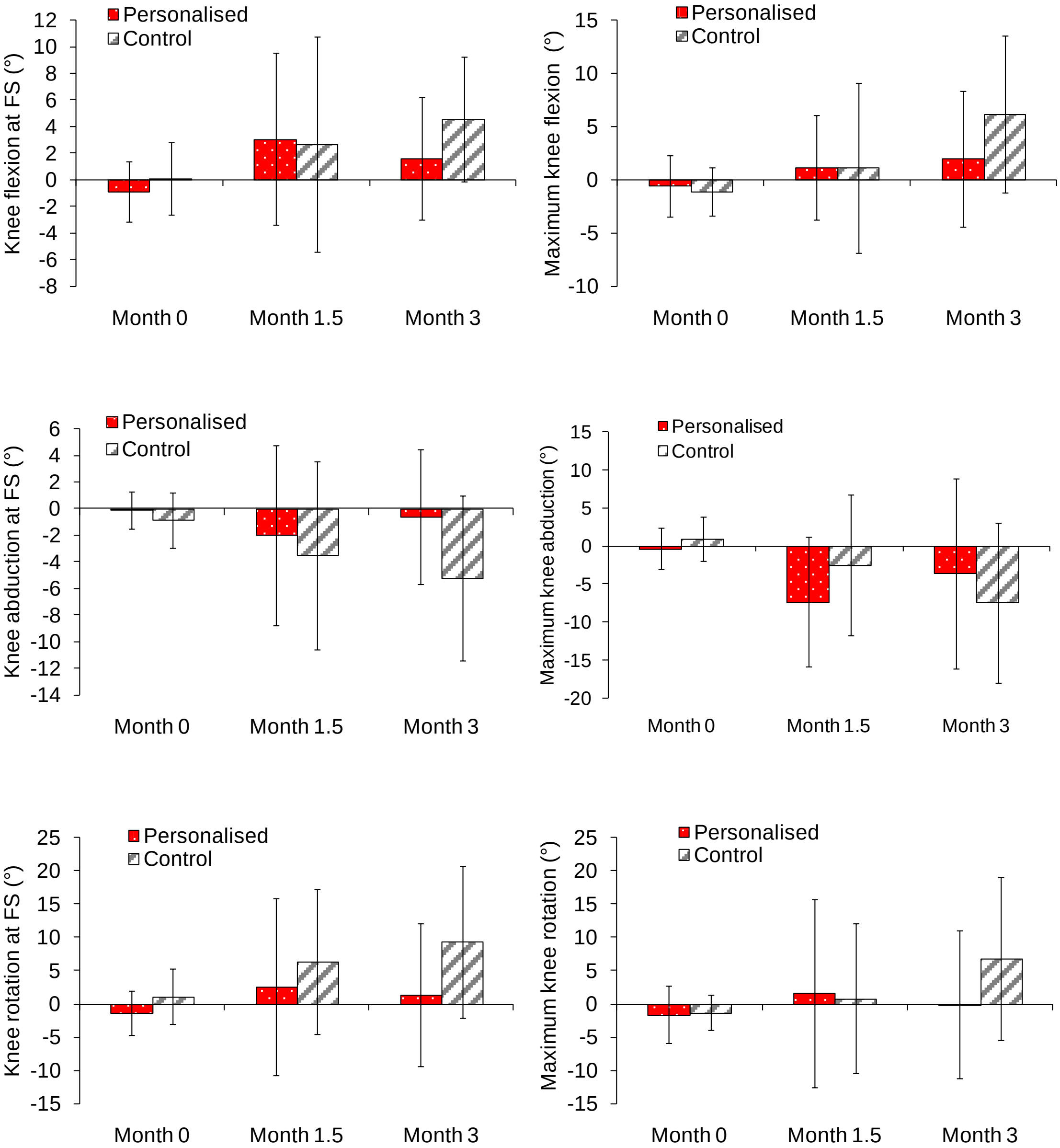


Figure 5.18. Knee kinematic parameters. FS = foot strike.

With regard to the GRF variables assessed (Figure 5.19), statistical analysis found significant main effects of the session number for impact peak ($p \leq 0.001$) with post hoc analysis indicating that the significant differences were between months 0 and 1.5 ($p \leq 0.01$) and months 0 and 3 ($p \leq 0.01$). Statistical analysis also showed significant main effects for 'session' for mean loading rate ($p \leq 0.01$), with post hoc analysis showing again that differences were between months 0 and 1.5 ($p \leq 0.01$) and months 0 and 3 ($p \leq 0.01$). Also, the mean loading rate was approaching significance for the experimental condition ($p = 0.057$), with lower values for the personalised insoles. No other significant main effects were found for 'session' or experimental condition for the remaining variables. Also, no significant 'session' X 'condition' interaction was found any of the variables.

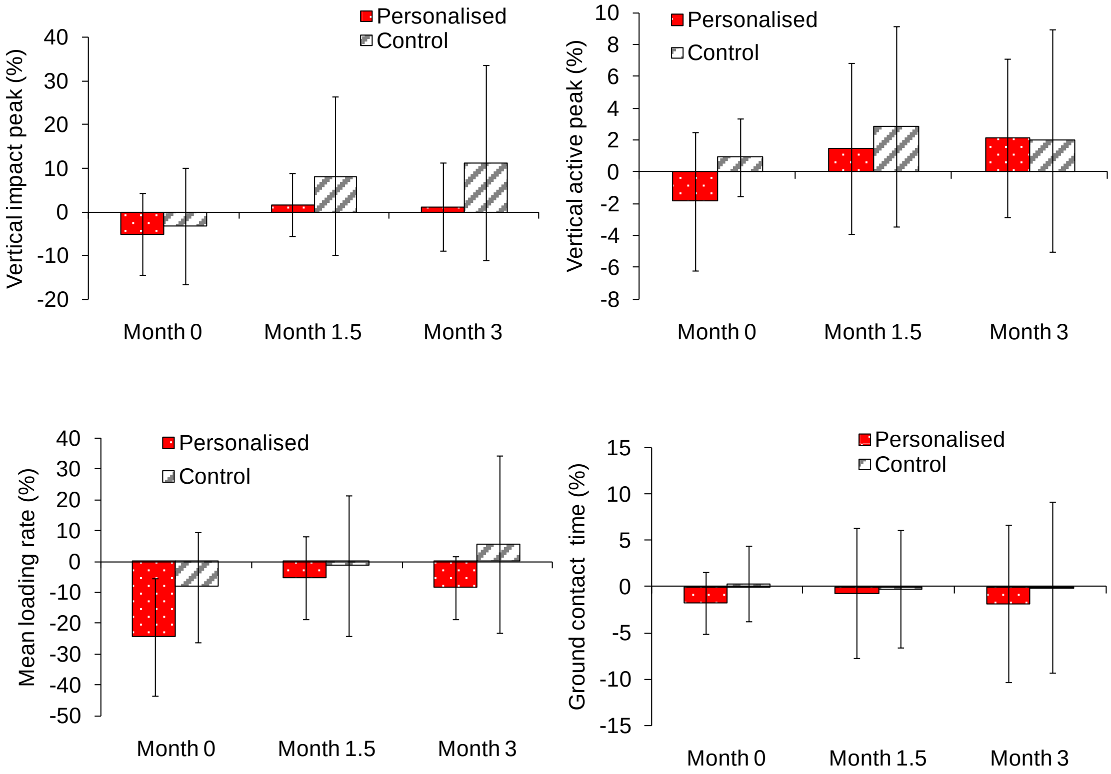


Figure 5.19. Vertical ground reaction force parameters.

With regard to the plantar pressure data, an increase of up to 250% was recorded in months 1.5 and 3 in comparison to month 0. This was clearly a problem with the data itself. The calibration files of all trials were then explored with the expectancy that they would explain this variation. Indeed, these files indicated an increase in saturation pressure and a decrease in the number of loaded cells in the 3 month period. The reasons for this were unknown as calibration was performed before each laboratory session as recommended in the F-Scan's user manual: standing, with individuals transferring 100% of their body weight to the pressure sensors. At this stage, the manufacturer (Tekscan Inc.) was contacted to further understand the issue. After an exchange of e-mails, it became clear that the increase in saturation pressure and decrease in number of cells were likely to be due to the degradation of the sensors. The manufacturer indicated that, depending on the nature of the testing, the sensors should be considered as disposable. Unfortunately, a procedure for the systematic replacement of sensors was not in place nor would indeed have been practical due to cost constraints. It was therefore, decided to only consider the data from the first session for analysis, where data were recorded with participants wearing both the original and experimental (personalised or control) insoles using the same sensor. Using the paired samples Student's *t*-test, significant differences in peak mean pressure were found between the conditions underneath the heel region ($p \leq 0.01$), whereas mean plantar contact area was approaching significance ($p = 0.056$). No significant differences were detected between conditions for midfoot and forefoot peak mean pressures (Figure 5.20).

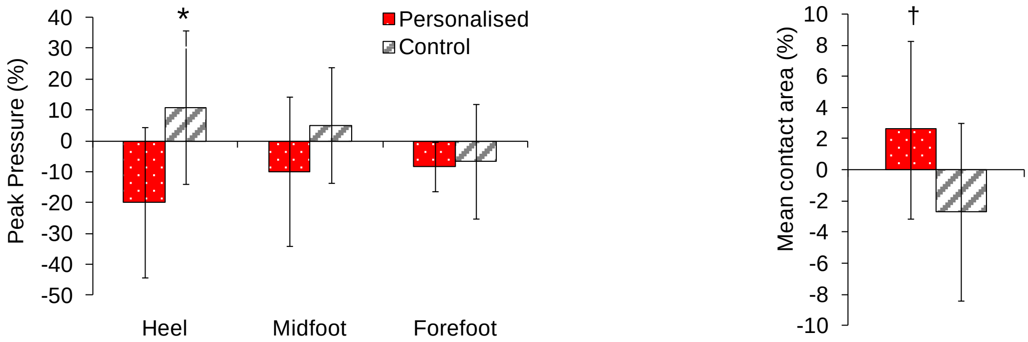


Figure 5.20. Peak mean pressure and mean plantar contact area. (* $p \leq 0.01$; † $0.05 \leq p \leq 0.1$).

5.5.4. The personalisation process

The findings concerning the personalisation process shown in Figure 5.3 are now presented starting with the foot capture phase (3-D scanning and anthropometric measurements), followed by the additive manufacturing technology itself (insole design and manufacture).

5.5.4.1. Foot capture

In this study, positioning the foot for the scan took about 3 minutes. This is longer than the pilot (2 minutes) not only because the individuals had to maintain a position of 90° at the ankle joint, with their lower leg perpendicular to the glass of the scanner and 10% of the weight bearing, but also because the participants had to practice this. The actual scanning of each foot took one minute, because the 4 cameras scan independently, one at the time and taking 15 seconds each to do a scan.

Taking the 15 anthropometric measurements of the foot manually took approximately 15 minutes and Table 5.4 shows these measurements. Student's *t*-tests revealed significant differences ($p \leq 0.05$) for only foot length from the heel to the 5th digit between the two conditions. It is unlikely that this difference alone would influence the discomfort and biomechanical data.

Table 5.4. Participants' anthropometric measurements. Data presented as mean (in millimetres) (SD).

Condition	Personalised (n = 13)	Control (n = 13)	p value
Foot length (1st digit)	250 (11)	246 (18)	0.295
Foot length (2nd digit)	250 (13)	245 (19)	0.372
Foot length (5th digit)	213 (10)	206 (16)	0.047
Metatarsale tibiale length	184 (8)	180 (14)	0.232
Metatarsale fibulare length	166 (9)	162 (13)	0.209
Foot breadth	95 (6)	95 (8)	0.971
Heel breadth	66 (5)	67 (6)	0.406
Dorsum height at 10%	54 (9)	55 (6)	0.422
Dorsum height at 90%	48 (7)	50 (5)	0.213
MPJ height	43 (6)	44 (9)	0.895
Hallux height	20 (2)	21 (3)	0.141
Navicular height	19 (5)	18 (5)	0.650
MPJ girth	237 (14)	240 (21)	0.506
Mid arch girth	239 (16)	244 (24)	0.440
Heel girth	321 (18)	320 (26)	0.866

There were no significant differences for the medial longitudinal arch values (Table 5.5). Further analysis of the relative arch deformation (RAD) data indicated that 2 runners in the personalised and 3 in the control had stiff arches, and 2 individuals in the control condition had a flexible foot. According to the arch ratio calculations, 4 participants in the personalised and 2 in the control condition were low arched, whereas only 1 participant (from the personalised condition) was high arched.

Table 5.5. Participants' medial longitudinal arch values. Data presented as mean (SD).

Condition	Personalised (n = 13)	Control (n = 13)	p value
Relative arch deformation	1.489 (0.788)	1.510 (1.200)	0.975
Arch index	0.074 (0.019)	0.074 (0.018)	0.778
Arch ratio	0.290 (0.042)	0.307 (0.029)	0.175

Statistical analyses indicated no significant correlations between the anthropometric measurements and discomfort ratings for both groups. For the biomechanical data, no significant correlations were detected for personalised condition, whereas in the control condition, significant positive correlations were detected between the vertical active peak and foot breadth, MPJ girth and arch girth (Table 5.6).

Table 5.6. Foot dimensions that significantly correlated with vertical impact peak (* $p \leq 0.05$; † $p \leq 0.01$).

Measurement	Month 0	Month 1.5	Month 3
Foot breadth	r = 0.774†	r = 0.643*	r = 0.746*
MPJ girth	r = 0.833†	r =0.622*	r = 0.723*
Arch girth	r = 0.831†	r = 0.651*	r = 0.659*

The total time for the foot capture phase (3-D scanning and taking anthropometric measurements) was approximately 25 minutes (Table 5.7).

Table 5.7. Approximated time required per individual to capture both feet.

Phase	Description	Time
1.	Positioning the foot to scan	6 minutes (both feet)
2.	Foot scanning	2 minutes (both feet)
3.	Identifying and marking of the anatomical landmarks	2 minutes
4.	Taking the anthropometric measurements	15 minutes
	Total	**25 minutes**

5.5.4.2. Additive manufacturing technology

In general, the scan data was compatible with the software and hardware used and presented less noise than the scans taken in the pilot study. Data manipulation (insole design using reverse engineering) took 1 hour and 30 min per pair. Geomagic Studio, the software used for the data manipulation (Figure 5.21) proved to have all the resources required: noise reduction, plane datum creation, deletion of the unwanted data, boundary and surface smoothing, data offsetting and data thickening.

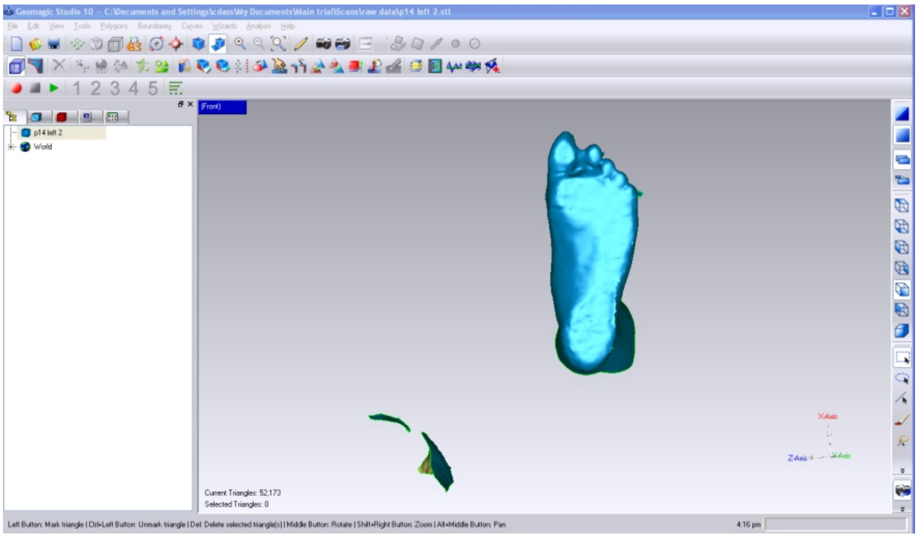


Figure 5.21. Screenshot of a raw triangulated data on Geomagic Studio software.

It is difficult to calculate the total time to manufacture all the 76 insoles, because they were not produced at the same time. In general, manufacturing time would depend on machine capacity, with a minimum of 3 hours. In order to check the accuracy of the personalisation process, a measurement was taken from one of the personalised insoles (chosen randomly) at the time of design and after manufacture, and a difference of 0.7 mm was found between them (Figure 5.22).

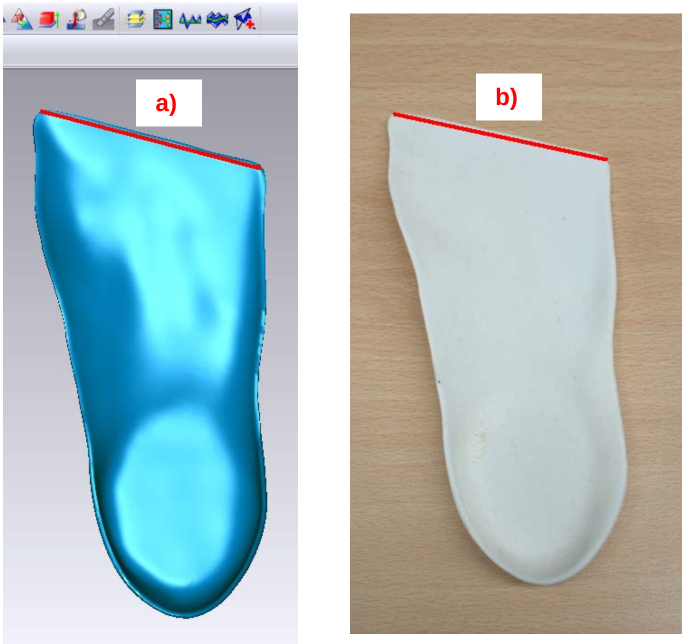


Figure 5.22. The personalised condition during the design phase (left) and after manufacturing (right). a) 79.7 mm; b) 79 mm.

The same measurement was carried out for the control condition, but this time including the trainer's original insole. The measurements indicated a difference of almost 3 mm between the original data and the final (Figure 5.23). Considering that during the manipulation phase the control insoles scan data were decreased to be 2 mm smaller to accommodate the added 2 mm thickness, the real difference between the original data and the AM insoles was in reality less than 1 mm, similar to the personalised.

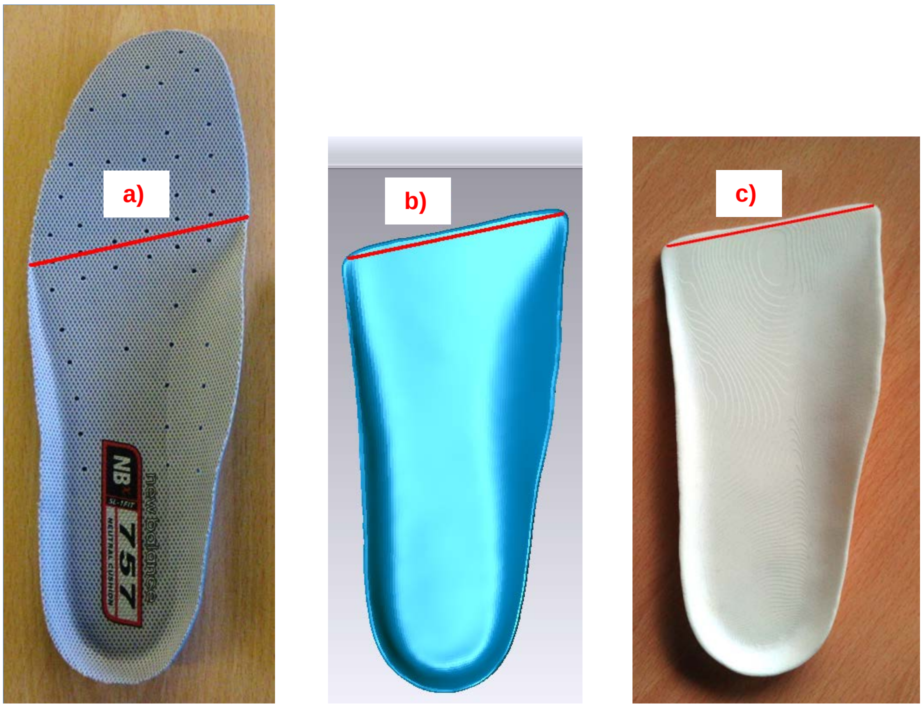


Figure 5.23. The control condition before the scan (left), during the design phase (centre) and after manufacturing (right). a) 96 mm; b) 94 mm; c) 93.2mm.

Nylon 12 showed very good durability over short and medium term use: no signs of breaks or cracks were found by the researcher during the visual inspections and hand manipulation in the laboratory sessions (Figure 5.24).

Figure 5.24. Bottom views of the (a) control and (b) personalised insoles after 1.5 (top images) and 3 months (bottom images) of usage.

5.5.5. Other participants

In total, 7 participants, 4 from the personalised and 3 from the control condition, discontinued the study. Tables 5.8 and 5.9 give a summary of their characteristics and the reasons given by them. As can be seen, the main reason was discomfort reported under the arch region (2 from the personalised and 2 from the control). All of these participants contacted the researcher when 'not comfortable at all' was reported on the VAS of the Activity Diary (as instructed by the researcher). They were then told to stop wearing the trainers and were withdrawn from the research. Two further participants (1 from personalised and 1 from control), were difficult to contact despite efforts to reach them via e-mail and telephone. The final participant discontinued after trying several shoe sizes, but none would fit her foot well enough. She informed the researcher that she could not continue to wear the model of trainers provided.

Table 5.8. Descriptive characteristics of the participants from the personalised condition that discontinued the study.

Condition	Personalised			
Participant Number	1	2	5	7
Gender	Male	Female	Male	Female
Age (yrs)	26	23	38	43
Height (cm)	178	172	182.4	161.4
Body mass (kg)	75.3	68.5	80	61.2
BMI	23.8	23.2	24	23.5
Shoe size (UK)	8	6	8	7
Running per week (km)	48	30	19	40
Reason for discontinuing	Discomfort under the arch	Discomfort under the arch	Not provided	None of the shoes tried would fit properly.
Week discontinued	3	2	Between 1-6	1

Table 5.9. Descriptive characteristics of the participants from the control condition that discontinued the study.

Condition	Control		
Participant Number	3	4	6
Gender	Female	Female	Male
Age (yrs)	39	41	26
Height (cm)	164.9	158.8	175.6
Body mass (kg)	60.9	66.6	78.4
BMI	22.4	26.4	25.4
Shoe size (UK)	6.5	5.5	8
Running per week (km)	29	48	40
Reason for discontinuing	Discomfort under the arch	Discomfort under the arch	Not provided
Week discontinued	7	3	Between 7-12

It was decided to keep the 5 unpaired participants in the study, in case their data could potentially be used to pair with anyone else (Table 5.10). Although this did not happen in the end, their discomfort and Activity Diary data were compared between conditions as ‘groups’ (i.e. not paired) to identify any trends or patterns that could differ from the data of the 13 pairs. However, these analyses confirmed the findings of the ‘paired’ data, with the control insoles having higher discomfort ratings in comparison to the personalised and the arch showing higher discomfort in both conditions.

Table 5.10. Descriptive characteristics of the unpaired participants that completed the study.

Condition	Personalised (n=2)	Control (n=3)
Age (yrs)	29 (0)	30.7 (8.9)
Height (cm)	171.2 (12)	180.9 (14.3)
Body mass (kg)	73.2 (13)	78.5 (16.1)
BMI	24.9 (1)	23.8 (2.2)
Shoe size range (UK)	6.5-9	3.5-11
Running per week (km)	33 (32.5)	21 (7.9)
Gender	1M and 1F	2M and 1 F

5.6. Discussion

The main aim of this longitudinal study was to evaluate the short and medium term use of personalised insoles in terms of discomfort and biomechanics of the lower extremities. Therefore, the results in terms of these variables will be first approached, followed by a discussion of the personalisation process.

5.6.1. Discomfort

The data showed that the personalised insoles had less reported discomfort when compared to the control for almost all the aspects. For the heel and fit, significant differences between conditions were detected and these ranged between 8-25 discomfort points (Figure 5.12), whilst for the forefoot and midfoot the difference was approaching significance. In addition, a pattern could be noted that for all the aspects evaluated, the personalised condition had lower ratings of discomfort.

There are potential explanations for these findings. The heel cup depth of the personalised insoles used in the study was 15 mm and may have given the participants the feeling of a good fit (therefore lower ratings for heel and fit discomfort) and that the foot was being stabilised. In the control condition, the heel cup was also 15 mm and, because it was a generic shape based on scans of the original insoles, the heel cup was wide, having the same width as the shoe. Thus, the control condition allowed the soft tissue in the heel to expand more laterally in comparison to the personalised. This is in accordance with recent evidence, which suggest that the amount of support in the heel and arch regions are the main factors involved in why individuals prefer prefabricated[1] contoured insoles compared with a flat insert (McPoil *et al*., 2011). The main reason attributed by the participants for the lower ratings of heel discomfort in the personalised condition was the sensation of good fit. Contradicting this finding,

[1] Prefabricated are mass produced devices that can be bought off the shelf (Crabtree *et al*., 2009).

Mundermann *et al.* (2003b) stated that fit does not play a role in comfort of foot orthoses. However, their results showed significantly higher comfort for the custom-molded orthoses (that matched the shape of the foot) in comparison to the other experimental conditions which were not customised, so even in their study it would be more accurate to say that fit played a role in comfort.

The trend for a reduction in forefoot discomfort (which was approaching significance) might be explained by the way the insoles were designed. The length of the personalised glove fit insoles were designed to finish at the metatarsal heads, thus allowing the foot to flex at the MPJs. On the other hand, the control insole terminated at a standard point determined from the original insoles, but not necessarily matching the individuals' MPJs. As a consequence, some individuals possibly had to overcome extra resistance at this joint to bend the shoes, leading to the discomfort. Also, the forefoot is the region that experiences the highest forces (Cavanagh, 1980), so even slight differences in design between the two conditions could be more easily perceived.

The arch area in both the personalised and control insoles were reported as 'intrusive' and 'too hard' by the participants, similar to reports in the literature on laser sintering (LS) inserts made of Nylon 12 (Pallari *et al*., 2010). This is reinforced by the fact that 4 participants discontinued the current study because of discomfort in this region. The foot capture position (10% of weight bearing) may have contributed to the higher ratings of discomfort under the arch, coupled with the fact that the 2 mm thickness made them rigid. These contributed to the insoles functioning like an orthotic, restricting the natural movement of the arch, which is spring structure capable of storing energy elastically (see Chapter 2; Alexander, 1987), during the stance phase. The material used in this study was rigid (Shore D 73) and, according to Crabtree *et al.* (2009), a high density material will have little cushioning so will provide a rigid and often controlling structure in comparison to a low density material which will absorb shock. In addition, the medial plantar arch has a lower pain pressure threshold[2] in comparison to the other plantar regions of the foot because it has less contact with the ground (Xiong *et al*., 2011). The lack of significant differences for arch discomfort between both conditions may be also linked to the lack of significant differences for overall discomfort. From the 13 pairs, only 9 pairs rated both overall and arch discomfort reduced for the personalised 'glove fit' insoles in the first session (for the other aspects, this ranged between 11 and 12 participants). In this case, if only one aspect of the

[2] Pain pressure threshold is defined as the pressure at which subjects judge pressure as uncomfortable (Johansson, as cited by Xiong *et al.* (2011)).

insole is uncomfortable (the arch in this case), the wearer tends to rate the overall insole as uncomfortable, even if all the other aspects are comfortable. This reinforces the need to assess different sections of the foot when evaluating discomfort. It is also interesting to note from the results that overall and arch discomfort ratings were the only ones showing significant main effects for ‘session’. The height and stiffness of the arch support was found to be intrusive at the start of the trial, but after 1.5 and 3 months participants became used to it and their perception changed. The data from the Activity Diary supports this, especially with regard to ratings of discomfort in the arch, indicating that participants could accommodate to a more ‘intrusive’ arch design. Thus, it is likely that individuals need a period of adjustment with any footwear. Contradicting these findings, Davis *et al.* (2008) reported that the largest difference in mean comfort ratings between semi-customised and customised orthotics was in the arch region. The customised orthotics indicated higher comfort ratings, but also showed the highest standard deviation, so significant differences could not be detected. However, the orthoses they used were made of graphite and were semi-rigid, whereas the ones used in this study were made of Nylon 12 and were rigid (Shore D 73). Chen *et al.* (1994) reported that the least comfortable insoles of those tested with 14 individuals were the very hard and inflexible, suggesting that the cushioning and flexibility of a shoe sole may be important factors for comfort. Similarly, Mundermann *et al.* (2001) reported that hard inserts with a higher arch (similar to the ones provided in this study) and inserts with viscous material were more uncomfortable in comparison to soft inserts with elastic materials. These studies evidence the influence of the material hardness on comfort perception and suggest that perhaps with a change in material in the arch region, significant differences in discomfort between conditions could be detected in this study. Supporting this assumption, McPoil *et al.* (2011) reported that using prefabricated foot orthoses made of EVA, there was significantly more comfort for insoles with an arch and heel support in comparison to flat inserts made of the same material for both healthy individuals and individuals with patellofemoral pain. However, it has been speculated that people can only distinguish the difference in material hardness if this difference is more than 30% (McPoil *et al*., 2011).

When analysing the discomfort data within conditions, ratings for the personalised insoles were significantly reduced during the 3-month period for all the aspects of the foot assessed, apart from the midfoot region. Ratings of discomfort in the control condition were significantly reduced over time only for the overall aspect, while the forefoot ratings significantly increased in month 3 in comparison to months 0 and 1.5. In a similar study (Mundermann *et al*., 2001), where 206 military personnel wore their preferred off the shelf insoles for 4 months, it was found that just by adding an insert to the boots, comfort was significantly increased in comparison to a non-insert condition. Based on this research and on the literature, it is possible to make some definitions regarding footwear comfort:

- a reduction in discomfort does not necessarily bring about feeling of comfort (Helander and Zhang, 1997);
- however, great discomfort is only experienced if the level of comfort is low (Helander and Zhang, 1997);
- good fit, perception of comfort in the heel and arch are the most important aspects that will dictate overall footwear comfort;
- if only one region is uncomfortable, the overall shoe may be seen as uncomfortable, even though the other regions are comfortable.

Although the VAS used in the Activity Diary was the same as that used in the laboratory sessions, the discomfort ratings in the Diary suggest something interesting. The ratings were visibly lower in the Diary than those reported in the laboratory sessions (Figures 5.12 and 5.15). One reason for this may be that in the Activity Diary individuals were asked 'if they felt any discomfort during the training session' and if they answered 'no', they were told not to complete the VAS. Therefore, it is possible that participants only responded 'yes' if discomfort was clearly perceptible. In the laboratory sessions they were asked to complete the entire VAS and perhaps felt more obligated to report any discomfort no matter how small.

Although the discomfort data showed significant differences between conditions and clear patterns, it would be interesting to understand whether the individuals would have had the same perceptions walking with the shoes instead of jogging/running. In a study of 41 individuals evaluating 3 running shoe models (cushioning, lightweight and stability), Kong and Bagdon (2010) found that runners preferred the same model for both walking and running. This is supported by other studies that also did not find significant differences in comfort between walking and running (Chen *et al*., 1994; Mills *et al*., 2011). Kong and Bagdon (2010) also reported that shoe model preference is significantly associated with sex, but not by running experience or body mass: women tended to prefer lightweight shoes, whereas men were 2.05 times more likely to choose the more cushioned model. However, in their study, participants only ranked the shoes according to 3 models available from the same manufacturer (Spira Footwear Inc), so that these findings may not be applicable to other brands.

In summary, it is relatively challenging to compare specific data between studies involving orthoses/insoles not only because there are clear differences in materials, hardness and shape, but also because of samples differences (runners, walkers, (a)symptomatic individuals, and so on). However, the discomfort data in the current study has clearly indicated that just a change in geometry of the insoles can provide benefits in terms of short and medium term use. The discomfort ratings showed significant main effects for experimental condition for heel and fit, while the forefoot and midfoot were approaching significance, with the personalised insoles showing reduced values. These ratings also decreased over time. The participants from both conditions indicated discomfort in the arch area. For that, potential solutions could include: change in the foot scan position (e.g. amount of weight bearing or dynamic scan), manipulate the arch area more specifically in the design phase or change in material in the arch region. These will be further discussed in Section 5.6.3.

5.6.2. Biomechanics

Analysis of the biomechanical data indicated that the changes occurred mainly at the impact phase (i.e. between 0 and 20%) of the ground contact and at the ankle joint. The literature is inconsistent with regard to these findings. MacLean *et al.* (2006) tested custom made orthoses in 15 healthy female runners and reported that changes in lower extremity dynamics occurred primarily in the initial stages of the stance phase, whereas in contrast, Mundermann *et al.* (2003a) speculated that molding orthotics plays a significant role in the kinematics during the late stance phase. As already discussed, it is generally difficult to compare the biomechanics of insoles between different studies given that often they vary in geometry and material and the authors do not always indicate whether changes have occurred because of either or a combination of both.

In the present research, individuals in the personalised condition presented significantly less ankle dorsiflexion (between 2° and 4°; $p \leq 0.05$) at foot strike (Figure 5.17). In a study involving 15 males, Nigg *et al.* (2003) also found that ankle dorsiflexion was significantly reduced by 1.0 and 1.2° for full medial and full lateral inserts, compared to a neutral condition. In addition, Nurse *et al.* (2005) detected a significant decrease of 0.6° in ankle dorsiflexion at touchdown with textured insoles, in comparison to a control condition. According to De Wit *et al.* (2000), flatter positioning of the foot is a strategy adopted to reduce plantar pressure under the heel, as a more horizontal foot placement covers a larger initial plantar area. Indeed, a significant decrease in heel pressure (Figure 5.20) was found in this study and confirms this theory. De Wit *et al.*

(2000) also reported a more horizontal foot placement for a barefoot condition in comparison to a shod condition which they speculated to be due to larger knee flexion and a more vertical position of the shank to the surface in the barefoot condition. However, knee flexion was not significantly different between conditions and the position of the shank was not analysed in the present research. Another explanation for the decrease in ankle dorsiflexion at foot strike can be a theoretical increase in sensory feedback provided by the heel cup in the personalised condition. In this case, a flatter foot placement would be a result of a strategy to mitigate large amounts of sensory input in the heel, similar to what Nurse *et al.* (2005) described when using textured inserts. The decrease in heel discomfort with the personalised condition could also be a result of this 'increased sensory feedback', but there is no conclusive evidence in this respect.

The biomechanics results did not show significant main effects for both 'session' and 'condition' for maximum ankle dorsiflexion. Although MacLean *et al.* (2006) found a significant reduction in maximum ankle dorsiflexion angle wearing orthosis which could be due to a slight heel lift provided by their orthotic conditions, that were 2 mm thick and hard. Limited range of motion of the ankle in the sagittal plane has been linked with development of foot pain (Warren and Davis, 1988). Johanson *et al.* (2006) reported that heel lifts of 6 mm and 9 mm increased ankle dorsiflexion excursion by on average 0.68° and 1.23° respectively in 26 subjects. They speculated that an increase of 1° in ankle dorsiflexion excursion during gait can represent a significant reduction in the stress on structures. Unfortunately, ankle dorsiflexion excursion was not assessed in this study.

The ankle kinematic data also showed significant main effects for experimental condition for maximum eversion, with the personalised insoles having the potentially positive effect of on average 1-2° less eversion. In a longitudinal study which evaluated the use of custom foot orthotics in female runners, MacLean *et al.* (2008) reported that after 6 weeks of intervention, the orthotic also significantly reduced maximum rearfoot eversion. Unfortunately comfort was not assessed in their experiment, although they reported that the orthotic decreased pain over time (no more information about this 'pain' was provided). In a similar study by the same group, MacLean *et al.* (2006) recruited 15 injury free female runners and documented a significant, yet small (approximately 1° in their case) decrease in maximum rearfoot eversion when wearing the orthotics, compared to a control condition. Davis *et al.* (2008) also reported that 8 of 19 individuals demonstrated a 2° reduction in maximum rearfoot eversion with a customised orthotic compared to a non-orthotic condition in healthy runners. These studies with orthoses reinforce the assumption made earlier that the personalised insoles were acting like an orthosis, restricting movement in the ankle joint. Nevertheless, as exposed in Chapter 2, subtalar pronation (which eversion is part of) is important to attenuate the impact forces between the foot and the ground (Hreljac, 2004) and this component is only injurious when it reaches excessive values. Despite the fact that the smaller maximum eversion found in the present study follows the literature on orthoses (according to Nigg *et al.* (1999), this is between 2-3°), the main question is whether this is relevant in terms of function. Considering that the sample for the study was asymptomatic runners without a recent history of overuse injuries, it remains unclear of the effect of these reduced values in terms of the development of injuries. Finally, although the arch support in the personalised condition has been suggested by the podiatrists consulted to have benefits by providing support, one study has shown that the effectiveness of arch-support orthotics was limited as there was no effect on strength or standing posture after a 2 month intervention (Kelaher *et al*., 2000).

With regard to knee kinematics, there were significant differences between month 0 when compared to months 1.5 and 3 for most of the parameters. This may be as a result of adaptation by the participants to both insoles over time. Between conditions, the only significant difference was for knee internal rotation at foot strike. Similarly, MacLean *et al.* (2006) reported no significant differences for knee kinematic variables (flexion, adduction and internal rotation) in 15 female runners wearing shoes with and without custom foot orthoses. Nakajima *et al.* (2009) also reported that adding an arch support to flat insoles did not change the kinematic (e.g. knee valgus angle) and kinetic (e.g. knee adduction moment) variables assessed in 20 healthy individuals.

According to the literature, changes in knee kinematic values during the stance phase are mainly linked with the amount of knee flexion and ground reaction forces. Higher knee flexion at foot strike can be observed for individuals running on surfaces providing higher mechanical cushioning, explaining the maintenance of the impact peak variables, as knee flexion ‘masks’ these changes (Dixon *et al*., 2000). Therefore, the lack of significant main effects for ‘condition’ for vertical impact peak in the present study was not likely to be the result of a compensatory strategy adopted by the runners, as there were also no significant main effects for knee flexion angle at both foot strike and maximum values.

The 3 vertical GRF variables analysed in this study (vertical impact peak, mean loading rate and vertical active peak) are thought to be related to increased overuse injuries (e.g. tibial stress fractures) in runners (Hreljac, 2004; Milner *et al*., 2006) and, therefore, are the most common kinetic variables assessed to evaluate the outcomes of orthoses (McMillan and Payne, 2008). Although the strike index did not form part of the selection criteria in this study, according to the GRF data, all the runners recruited were rearfoot strikers (i.e. they exhibited the impact peak in the data). This is important to consider as there are significant differences in GRF variables between rearfoot, midfoot and forefoot strikers (Cavanagh and Lafortune, 1980).

Statistical analysis indicated no significant main effects for ‘condition’ for both impact and active peak, but the mean loading rate was approaching significance ($p = 0.057$), with reduced values for the personalised condition. In studies with orthoses, Mundermann *et al*. (2003a) found a significant decrease in maximum vertical loading rate and vertical impact peak, similar to MacLean *et al.* (2008) when comparing orthotics to a control condition. Smaller mean loading rate is of interest in runners as excessive values have been associated with the development of tibial stress fractures in female runners (Milner *et al*., 2006).

Despite the fact that vertical impact peak showed lower values for the personalised condition during the 3 months, no significant differences were found. This can be partially explained by the design of the insoles. Mundermann *et al.* (2003a) and McLean *et al.* (2008) captured the foot using the neutral suspension cast technique and posted the orthotics to provide correction, whereas in the present research the insoles were a glove fit, without providing any correction. Using a heel cup support similar to the ones in the current study, Creaby *et al.* (2011) also did not detect changes in the impact peak in walkers.

Although the insoles from both conditions were hard, it is unlikely that the vertical impact peak would have changed with the use of a different material. Evidence suggests that vertical impact peak remains the same even after changing midsole hardness: hardness is not indicative of better cushioning as humans can react (or use a strategy like flexing the knee), masking any changes in hardness (Nigg *et al*., 1987; Dixon *et al*., 2000). Therefore, loading rate is considered a better indicator of cushioning ability than peak impact force (Dixon *et al*., 2000).

The plantar pressure assessments over the 3 month period proved to be unreliable as for practical and cost reasons the systematic replacement of the sensors was not possible after each use. According to the F-Scan manufacturer, sensor life is reduced if it becomes wrinkled or folded during use. Between 1 and 7 uses from the sensor can be expected, hence it is considered re-usable or disposable, depending on the nature of the testing (Tekscan, 2008). The poor durability of the F-Scan sensor has been documented, with its cost-effectiveness questioned by other authors (Woodburn and Heliwell, 1996). However, it is important to stress that the F-Scan has been reported to demonstrate adequate reliability for clinical and research purposes (Mueller and Strube, 1996), but the literature reports that it is unsuitable for comparing data between two sensors (Woodburn and Heliwell, 1996), in agreement with the current study.

Because of these problems, only the peak pressure data from month 0 was considered for analysis. These indicated significantly lower values in the heel for the personalised condition compared to the control. As reported earlier, this difference may be related to the flatter foot placement (i.e. less dorsiflexion) with the personalised insoles, suggesting that this strategy was probably adopted to limit local pressure in this region (De Wit *et al.,* 2000). The lower values in heel pressure with the personalised insoles is in accordance with the literature, which reports that customised total contact insoles can reduce plantar pressure under the heel and forefoot, redistributing it to the midfoot, and are more comfortable than a shoe without such insoles (Chen *et al*., 2003; Yung-Hui and Wei-Hsien, 2005). Therefore, the lower values in heel pressure found in this study can also be related to the decrease in heel discomfort, but this needs further investigation. Yung-Hui and Wei-Hsien (2005) found that customised fabricated insoles can also attenuate the impact force and are more comfortable than the shoe alone. In the present study, the impact peak values were not significantly reduced with the personalised insoles. This can be explained by the fact that the impact peak variable is not necessarily connected to heel pressure: it is speculated that at the time of this first peak, not only the heel, but also the midfoot and forefoot structures participate in load bearing (Hennig *et al*., 1996).

Mean contact area was also approaching significance ($p = 0.056$), with the personalised insole showing a larger contact area. This may also be related to a less dorsiflexed ankle at foot strike as with this strategy, the initial ground contact covers a larger area. Likewise, Guldemond *et al.* (2006) reported a significant increase in plantar contact area with custom made orthoses in comparison to the shoe alone. In this study, the plantar contact area was assessed as a whole, without dividing the foot into regions, but it is likely that the significant changes occurred in the midfoot. For example, McPoil *et al.* (2011) reported that contoured orthoses increased the medial midfoot contact area in comparison to flat inserts in a group of 20 runners and no significant differences were found for the other regions.

Although the plantar pressure data collected in months 1.5 and 3 were considered unreliable and were not analysed, the literature suggests that there would be no significant main effects for ‘session’. In a study with 3 individuals, Verdejo and Mills (2004) reported an increase in plantar pressure only after 250 km of wearing the shoes, with a greater increase after 400 km. In addition, McPoil *et al.* (2011) reported no significant differences in plantar surface contact area after 3 weeks of usage of orthoses.

In general, it does not appear that the use of the trainers for the 3 month period affected its capability in absorbing shock, as the literature reports that change in ground contact time could be an indicator of shoe degradation (Kong *et al*., 2009). The life cycle of a running shoe is estimated as being between 480 and 800 km, depending on usage (Runner’s World, 2001; New Balance, 2011). As the participants wore the trainers for an average of 60 minutes per week, it is very unlikely that the New Balance trainers used by the participants deteriorated to a point that they lost their functionality and affected the ankle, knee and GRF variables, as this would need them to run more than 40 km per week. Kong *et al.* (2009) reported no significant differences between new and worn shoes (after 200 miles) for vertical GRF variables, maximum knee flexion and ankle dorsiflexion angle at touchdown.

In summary, the changes in biomechanical parameters occurred mainly during the ground contact phase. Ankle dorsiflexion, mean loading rate and plantar pressure could be linked with the significantly less discomfort in the heel and these variables showed similar behaviour to the literature on orthoses, even though the glove fit insoles were not manipulated to provide functional correction.

5.6.3. The personalisation process

The position adopted for foot capture was standardised in an attempt to reduce between-subject variation. The scans were taken with the participants seated, maintaining a 90° ankle joint angle, with the lower leg perpendicular to the glass of the scanner. This was visually estimated by the researcher. The 10% weight bearing on the foot was achievable because the thigh, shank and foot weight approximately 10%, 4.5% and 1.5% of total body weight respectively (Dempster and Gaughran, 1967).

Also, the participants could practice the foot position and weight bearing using a weighing scale that was placed on the glass of the scanner prior to the scans. In an interesting study which compared foot positions similar to the ones adopted for both the pilot study and this current trial, Laughton *et al.* (2002) reported that partial non-weight bearing laser scans produced significantly lower (almost 90%) arch height in comparison to non-weight bearing scans. However, they also reported that the non-weight bearing laser scans were not reliable in capturing rearfoot and forefoot widths, maybe because of the difficulty in maintaining the same amount of ankle dorsiflexion between scans.

The literature is positive about developing orthoses using the position adopted in the current study because: (1) it requires less training and is easier to perform than supine non-weight bearing and prone non-weight bearing (McPoil *et al*., 1989); (2) it reliably captures the foot and is likely to produce an appropriate accommodative orthosis (Laughton *et al*., 2002); and (3) it has been shown to provide good results for pedal measurements and casting (Houston *et al*., 2006). Although there are a few studies that compare different foot positions, as discussed in Chapter 3 it is a concern that there is no guidance or consensus with regard to the optimal method of foot capture. In this direction, Pallari *et al.* (2010) reported that the amount of weight bearing during the scan may have a significant influence on the outcomes and suggested that the foot scan position should be decided by a podiatrist based on an individual assessment.

The time required to capture the foot was approximately 25 minutes, 6 minutes less than the pilot study. The experience gained by the researcher during the pilot study in marking and taking the manual measurements is the most important contributing factor for this reduction. Positioning the foot for the scan took about 3 minutes, whereas the scanning alone took another 1 minute per foot. In a study that scanned the head to build facial prostheses, Bibb *et al.* (2000) reported that the whole process of preparing the individual and taking 4 scans of the face took approximately 10 minutes using a light scanner, with scanning time of around 40 seconds per camera. In order to minimise any movement during the scan, they used a chin support for the face. However, the scan time of the present study can be considered excessive if compared to the laser scanner used by Houston *et al.* (2006), which captured the entire foot in 9 seconds. It is difficult to speculate the reasons for such discrepancy without further details about their equipment. The main information provided was with regard to the point density of the scanners which was similar (256 points per line). The important consideration about scan time is that it must be quick enough to avoid involuntary movement: if the position can be maintained comfortably, the speed is less of an issue. Hence, the 10% weight bearing adopted in this study helped brace against involuntary movement.

As with the pilot study, both manually collected anthropometric measurements and scan data were needed for 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 MPJs indicated the length of the insoles. In addition to these, the height of the navicular was used to determine the arch height of the insoles. In order to further explore the anthropometric data, statistical analysis was performed to detect any correlation between the measurements, discomfort ratings and biomechanical variables for the personalised condition, but no significant correlations were found. This is surprising as Mundermann *et al.* (2001) reported that arch height was significantly related to comfort perception. In their study, subjects with low foot arch rated a viscous and hard material higher than an elastic and soft material, whereas those with a high foot arch rated the elastic and soft material higher than the viscous and hard materials. However, it is possible that high or low arched individuals have distinct preferences, but a linear increase in discomfort with increased arch index for a given material may not exist. This would explain the findings of the present study as most of the runners recruited had normal arch height values. In the pilot study, relative arch deformation (RAD) significantly correlated with discomfort, which was not confirmed here. The difference in insole design between the two studies may have contributed to this inconsistency. As for further studies, it would also be interesting to assess only runners with high mileage per week or with high/low arches and prospectively analyse injury development over a longer period (> 6 months). In general, regarding anthropometric data, most of the measurements may not be necessary and as a consequence, the time required in taking them could be reduced significantly.

With regard to the insole design, the scan data were compatible with Geomagic Studio. This software provided the appropriate tools to reduce noise, delete unwanted data, fix the jagged edges on the boundary, smooth and thicken the parts to 2 mm. The final data file proved compatible with the AM machines. The podiatrists consulted by the researcher prior to the data collection mentioned that arch and heel cup support could provide benefits. Their input is supported by Pallari *et al.* (2010) who added arch and heel cup to support the orthoses for individuals with rheumatoid arthritis based on a systematic literature review. They stated that the heel cup would prevent the heel fat pad from collapsing, increase the effectiveness of the arch support, control the movement during the early stages of the ground contact and reduce pain. The arch support would provide realignment of the foot and increase its contact area with the orthoses, reducing plantar pressure from other regions. Very similar findings were found in the present study, in agreement to what the podiatrists envisioned. However, in relation to the arch support, it remains unclear whether this feature is really necessary for personalised insoles, especially if it is perceived to be intrusive and also possibly restricting the natural movement of the arch in healthy runners.

Although the insoles designed for this study were 2 mm in thickness, Pallari *et al.* (2010) reported that a 5 mm thickness offered ‘a good combination’ of strength and stiffness using the same material (Nylon 12). This difference can be due to the software, because in the pilot study, 3 mm was proven to be the ideal thickness and the insoles were designed through Magics software, whereas Pallari *et al.* (2010) utilised Magics CAD package and the present study used Geomagic Studio. Hence, it remains interesting for further studies to systematically compare the most popular reverse engineering software available on the market, such as FreeForm, Geomagic Studio, Magics CAD and so on, to understand their accuracy, advantages and disadvantages. Nevertheless, no further explanation of what Pallari *et al.* (2010) meant by ‘a good combination’ was provided, meaning that the insoles of the present study and the ones that these authors designed probably had different strength and stiffness properties.

The AM technology (LS) explored showed compatibility with the STL data and the degree of accuracy was estimated to be less than 1 mm. Although only one measurement was taken and only one insole per condition (personalised and control) was measured, the insoles were chosen randomly and so can give an indication of accuracy. The literature does not report much depth about the degree of accuracy for AM, suggesting that many factors may contribute to it. The ‘less than 1 mm’ found in this study can be considered a low accuracy if compared with the 0.1 mm reported by Bibb *et al.* (2000) using laminated object manufacturing (which is an AM technology) to build facial prosthesis from scan data. However, unlike facial prostheses the author believes that less than 1 mm is an acceptable accuracy for insoles. Also, as a general rule, the accuracy of LS is generally given as +/- 0.4 mm because this is the size of the laser spot typically used. Pallari *et al.* (2010) reported no differences in ‘fit’ and comfort perception between customised orthotics produced from the same design, but using different manufacturing techniques. One of the techniques used traditional methods and the other used LS, reinforcing the view that AM is ready to deliver personalised inserts to the high street. In addition, there are other AM processes commercially available that may provide a better solution for footwear. For example, some 3-D printing processes allow the production of insoles using multiple materials, which could answer the needs of using a stiffer material for the heel cup and a softer material under the arch (this will be further discussed in Chapter 7). As a potential alternative to AM, Crabtree *et al.* (2009) recently reported a methodology for the design and manufacture of personalised sports insoles and presented two novel manufacturing techniques which are more cost efficient than injection molding: cryogenic machining and autoclaving. According to the authors, the former involves altering the key characteristics of polymer foam materials by freezing them to very low temperatures (below the glass transition temperature), whist the latter uses pressure in a vacuum bag to bond the layers of carbon-fiber to build the orthotic.

With regard to the material used, Nylon 12 is a rigid nylon with hardness classified as Shore D 73. This material showed very good durability throughout the study: no signs of breaking were noted in the visual inspections during the laboratory sessions. Van Der Zande *et al.* (2010) used the same material for personalised high heeled shoes using LS, which provided bending for the forepart relative to the back part of the shoe and support for the midfoot, among other properties. However, no study was found by the researcher with regard to the development of functional footwear using this material, meaning that it may not be mature enough to produce such footwear and still needs to be subjected to materials testing under laboratory conditions.

One of the most important aspects of the insoles/midsoles is the hardness of material. This is a crucial variable that significantly influences discomfort and biomechanics as too rigid a material will offer no impact attenuation, whereas if too soft, the material will not provide enough support (Crabtree *et al*., 2009). The most common materials used for orthotics manufacture are: flexible, semi-rigid and rigid plastics (for example aquaplast, suborthylene and polypropylenes); foamed materials (such as polyurethanes and EVAs), which are also used in the manufacture of midsoles; and carbon-fibre plastics, which have extremely high stiffness to weight ratio (Neale and Adams, 1985; Crabtree *et al*., 2009). However, some studies report only the material type or give subjective indications about the hardness like ‘soft’ (Mundermann *et al*., 2001), ‘semi soft’ (Davids *et al*., 2008) or ‘hard’, which are not enough to contextualise, especially for comparative purposes. The hardness of a material is usually determined by its resistance to indentation and is generally presented in the Shore durometer scale, depending on the material type (the most common are Shore A and D). Having said this, there are also studies (e.g. Robbins and Waked, 1997; Hardin *et al*., 2004; Mills *et al*., 2011; Creaby *et al*., 2011) which report the actual material hardness of the insole/midsole being investigated.

5.6.4. Limitations

One of the main limitations of this study is the matched pairs experimental design. As discussed earlier, a repeated measures design would have been ideal, but this was not feasible mainly because of the time required. However, the fact that the runners were matched according to affective factors and the biomechanical data were normalised within individuals will help minimise the impact of individual variations. The lack of significant differences between participants in the two conditions for mean steps taken and mean usage of the trainers during the monitoring period also increases confidence in the findings.

Another limitation is using the Vicon System and PiG model for marker placement. In this model, almost all markers placed on the hip and leg are used to calculate the ankle joint centre, meaning that any errors in the proximal joints are transferred to the distal joints. This, added to the fact that in extreme cases skin may move as much as 25 mm over the skeleton due to its inherent elasticity and change in shape of muscle bulk under the skin (Macleod and Morris, 1987) can lead to inaccuracies in the data. These sources of inaccuracy are potential issues in every model, but in the PiG model they have a greater chance of occurring as the calculation of the knee and ankle joint centres are dependent on marker placement on the proximal joints. For this reason, a way of calculating the ankle joint centre using an additional marker on the ankle has been proposed (Nair *et al*., 2010), but a comparison between this methodology and the PiG values in terms of joint angles, moments and power is still to be validated. With this extra marker, the ankle joint centre would be calculated only by using two markers in medial and lateral malleoli. Another limitation with the data collected is with regard to the heel and toe markers, which should be placed on the participants' skin instead of the shoe, as movement of the shoe may not accurately represent movement of the foot. However, placing the markers on the skin would require cutting holes in the shoes, which could have implications on the findings as runners had to train with the same trainers. The final limitation with the motion capture system refers to potential between-session variability of both marker placement and system calibration, but a recent study has shown acceptable repeatability for trials between testing sessions (Queen *et al*., 2006).

5.7. Conclusions

The results indicate that personalisation of the geometry of the insoles alone can provide benefits. Lower reported discomfort ratings for the heel and fit were detected and there was a trend for lower discomfort in the forefoot and midfoot with the personalised condition when compared to a generic shape (control condition). The heel cup was beneficial by giving participants the sensation of foot stabilisation and good fit. On the other hand, the arch was considered as intrusive and too rigid by the participants and no significant differences in discomfort were detected for this aspect in comparison to the control. The higher discomfort ratings reported for both conditions under the arch is supported by Activity Diary and by fact that 4 runners discontinued the study due to this discomfort. Proposed solutions to increase comfort in the arch area include: changing the foot scan position, manipulation of the scan data, changing the insole material or even a combination of these. However, these still need further investigation.

Although the biomechanical parameters were not as systematic and as clear as the discomfort data, a pattern could be detected: most of the changes occurred during impact with the ground. The less ankle dorsiflexion at foot strike found for the personalised condition can be related to the significantly lower heel pressure and increase in plantar contact area. The personalised insoles also led to between 1 and 2° less maximum eversion, but it remains unclear whether this small change is relevant in terms of reducing injury risk especially in healthy individuals. The significant main effects for ‘session’ for the knee kinematics could be a result of ‘adaptation’ in both sample groups.

In terms of the process, approximately 25 minutes were required for the foot capture phase, with scanning taking 2 minutes in total, plus 6 minutes to position the feet. Although the foot posture adopted may not be considered ideal, the literature reports good results in terms the development of orthoses. Surprisingly, only 3 measurements (foot length from the heel to the 1st and 5th MPJs and navicular height) proved to be useful to the design and specification of the personalised insoles. No significant correlations were detected between the anthropometric measurements, discomfort ratings and biomechanical variables for the personalised group. This indicates that the time required to take the anthropometric measurements could be reduced substantially.

The reverse engineering software (Geomagic Studio) provided all the required tools for manipulation of the data, but it is still necessary to systematically compare the most popular CAD packages to understand the advantages and disadvantages of each for a given task. Based on the discomfort ratings and the literature, the material used (Nylon 12) proved to have good durability, but it is probably too rigid for the development of insoles or footwear particularly for under the arch area.

Finally, the results of this study showed the potential benefits of the short and medium term use of the personalised insoles in terms of discomfort and lower extremity biomechanics. However, it is important to highlight that these findings may only be applicable to the methodology (i.e. foot position, insole design and material) and to the sample (i.e. healthy runners) recruited. Further research is needed, mainly with regard to the personalisation process. These include: optimal reverse engineering software, foot capture position and insole material.

Chapter 6: Case study: feasibility of a dynamic scanner

6.1. Introduction

Chapter 3 evidenced the need to capture the foot in a way that is representative of its dynamic nature, taking into account changes in shape during ground contact. For instance, foot contact area with the ground (length and width) increases as weight increases, whereas arch height and arch angle decrease significantly between static weight bearing and weight bearing during walking (Hamill *et al*., 1989; Tsung *et al*., 2003). The longitudinal study (Chapter 5) reinforced this concept as discomfort was reported in the arch region because it was considered as 'too hard' and 'intrusive' by the participants. Among the solutions, the need to explore different foot scanning positions was proposed. For this, dynamic foot scanning would be the ideal alternative, but these types of systems have been reported as expensive and exclusive, leaving their application to footwear design largely unexplored in the academic literature.

In this context, the author met Mr. Timo Schmeltzpfenning from the Biomechanics Research Group at Tuebingen University, Germany, at a conference in Miami, where the author of this thesis presented a paper on the preliminary findings of the research (Salles and Gyi, 2010). Timo presented a paper on a novel scanner capable of capturing the human foot dynamically, together with anthropometric measurements taken from 144 individuals using such a scanner (Schmeltzpfenning *et al*., 2010). After some discussion, the opportunity to combine both complementary and novel techniques (dynamic scanning and additive manufacturing) on footwear development was identified.

The main aim of the case study presented in this chapter was to explore foot capture using a dynamic scanner for the design and manufacture of insoles using additive manufacturing (AM) (adding to Objective 1 of this thesis). In addition, it provided an opportunity to gather *ad hoc* data on the short term use of personalised insoles in terms of comfort. However, due to time and costs constraints, this case study could only ever be a starting point looking at the footwear personalisation process using dynamic scanning.

6.2. Research method

6.2.1. Study design and rationale

In January 2011, the author and Dr Candice Majewski, another member of the Elite to High Street team from the Additive Manufacturing Research Group, visited Tuebingen University to see the dynamic scanner and meet the Biomechanics Research Group to discuss conducting a small study. In agreement with what was reported in Chapter 5, it was identified during this meeting that 3 main variables influence insole comfort and function: (1) foot scanning position (or the design combining multiple frames in the dynamic scanning), (2) data manipulation using a CAD package and (3) material(s). Because this was an opportunistic case study, the researchers decided to explore only the first variable (foot scanning position) by developing 4 different insoles from the dynamic scan data (this included 1 static design). These designs and the reason(s) for their development will be detailed in Section 6.2.2.1.

The dynamic foot scanner consisted of 5 modified projector camera units (model: z-Snapper; ViALUX GmbH, Germany) positioned surrounding a glass plate (0.6 x 0.4 m) where the foot is captured during ground contact. The scanner has a 4.6 m walkway, which is 0.8 m from the floor. The proposed measurement system is based on a structured light method combined with area triangulation in a synchronised scanner set up. This multi-sensor system is called DynaScan4D and was developed in a project between Vialux and the Department of Sports Medicine at Tuebingen University. The general accuracy of the system is good (below 1 mm) for the generation of the point cloud. On average, the entire surface of the foot is captured three-dimensionally at a rate of 46 frames per second, with cameras synchronised generating an average of 36 point clouds as a roll over process during walking takes about 0.6 to 0.8 seconds. Figure 6.1 shows the scanner together with the location of the cameras; there is 1 camera underneath the glass to capture the plantar view of the foot. A full description and specification of the scanner is provided by Schmeltzpfenning *et al.* (2010).

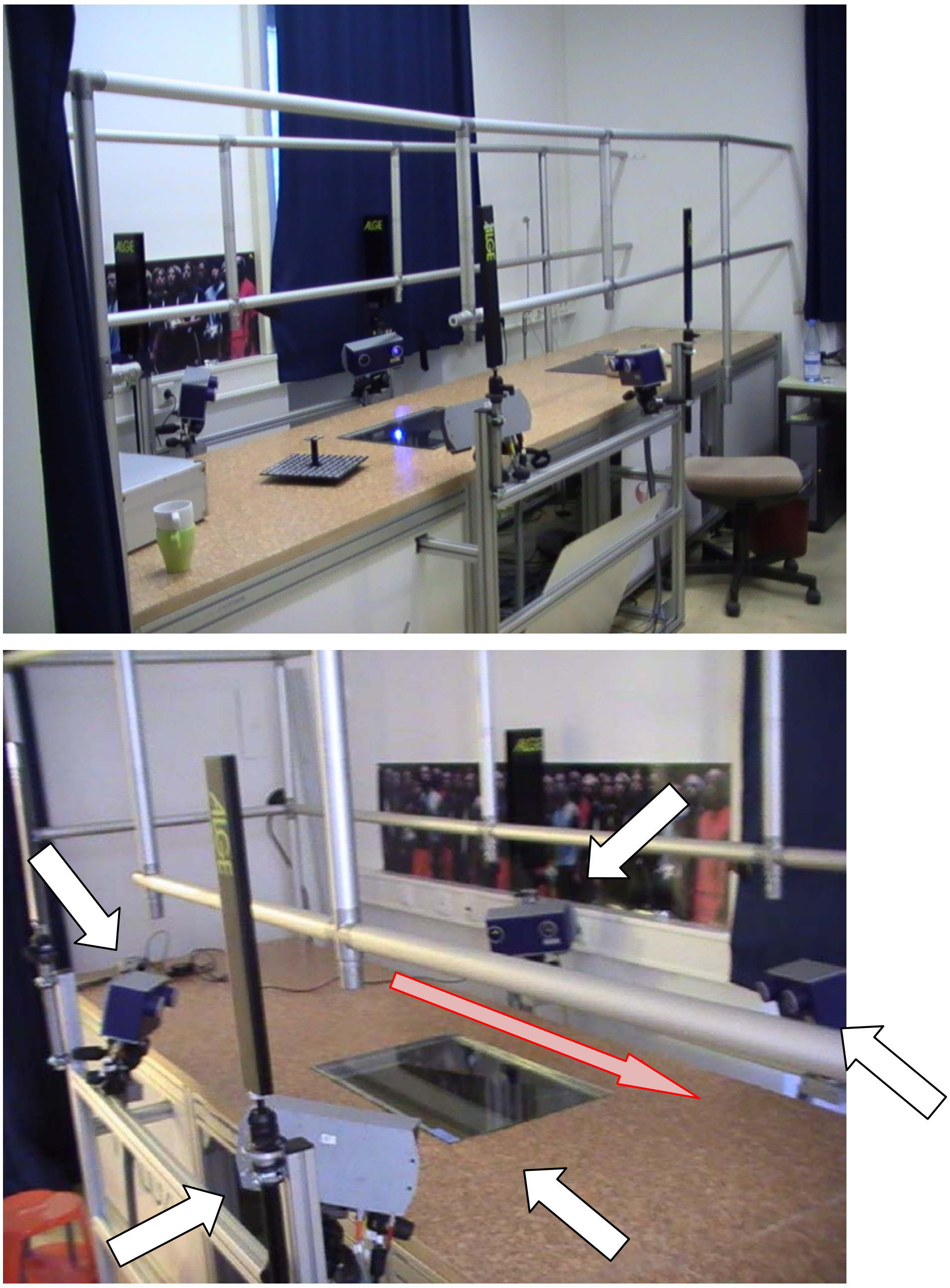


Figure 6.1. Dynamic scanner used in the study. Top image shows the entire view of the scanner. Bottom image indicates the location of the cameras (white arrows) and the direction of walk (red arrow).

This case study was mainly conducted to explore using the dynamic scanner itself in the personalisation process (i.e. capturing the foot using a dynamic scanner, insole design and manufacturing of the parts). Due to time and costs constraints, a small and convenience sample of 4 researchers (2 from Tuebingen University and 2 from Loughborough University) was used. It was decided by the team to fabricate full length insoles as including the toe region could expose further challenges in the design phase of the personalisation process. In addition, the participants ranked the insoles from the most to the least comfortable, which allowed a quick assessment of comfort and reproduced a typical footwear purchase experience, when customers select a few models of shoes to try and buy the most comfortable. The insoles were ranked according to the comfort in the heel, midfoot and forefoot. The longitudinal study (Chapter 5) found that analysing only overall comfort may hide potential (un)comfortable regions.

The personalisation process itself was evaluated as in the previous studies. The foot capture element was assessed with regard to the compatibility and quality of the scan data and through the comfort rankings. The AM technology phase was evaluated with regard to the time to design the insole and the capability of the CAD software (Geomagic Studio) to process the data. The insole material (Nylon 12) used was evaluated from the comfort assessment.

6.2.2. Study procedure

In order to capture each participant's feet, they were asked to walk 10 times (5 for the left and 5 for the right foot) across the scanner's walkway at a self selected speed, landing with either foot on the glass of the equipment, while it was scanned at 46 Hz. The trial was accepted if the correct foot contacted the entire glass and no obvious alteration of the gait pattern was noticed. Five scans from each foot were necessary due to a potential variation in the quality of the data depending on speed and accurate placement on the glass, thus the trial containing the best point clouds (i.e. more foot detail) was selected for the insole design.

Participants then had their feet captured statically for the 'static' design. For this, they sat on a chair with adjustable height and lightly rested their foot on the glass of the scanner with approximately 10% of weight bearing, maintaining 90° at the ankle joint and the lower leg perpendicular to the glass of the scanner (Figure 6.2), following a similar procedure as reported in Chapter 5 (Section 5.3.3.1). This procedure was repeated for each foot.

Figure 6.2. Participant having the foot scanned for the static design.

After the insoles were manufactured, 8 pairs were sent to Germany, engraved with both participant's name and design type (using a code). One of the German researchers was responsible for collating the comfort data in Germany, while the author collated the data in the UK. Each researcher (participant) was asked to walk for approximately 20 metres using each insole design and ranked them in terms of heel, midfoot and forefoot comfort. The order of the insoles was randomly assigned and the participants were blind to the experimental conditions. In addition, they wore their own trainers fitted with the original insole between each 'condition' for this case study. Therefore, the order of the insoles for the comfort assessment was: X-Y1-X-Y2-X-Y3-X-Y4, where X is the original trainers' insole and Y corresponds to the 4 insole designs (randomly assigned). Using the original insole provides the same comfort baseline for all the conditions, as Mundermann *et al.* (2002) has reported that an insert is tested after an uncomfortable insert it may be seen as more comfortable compared to being tested after a comfortable insert (see Chapter 3).

6.2.2.1 Insole design and manufacturing

From the scan data, 4 insole designs were made (described below): 3 from the dynamic and 1 from the static data. In common, all the insole designs followed the same procedure used in the longitudinal study, that is: manipulated (using Geomagic Studio, version: 10; Geomagic, Inc, Durham, USA) to rectify and delete unwanted data, but aiming to preserve the original geometric accuracy. Therefore, data were 'cleaned' to remove unwanted 'noise', smoothed, thickened to 2 mm, engraved to a depth of 0.5

mm (to help the identification of the parts) and converted into a stereolithography (STL) file. A height of 15 mm for the heel cup was again stipulated, and in this study a height of 4 mm was chosen for the forefoot (i.e. the region beyond the ball of the foot). After this design phase, the parts were manufactured at Loughborough University from Nylon 12 (DuraForm PA®) using laser sintering (LS), following a process similar to Chapter 5 (Section 5.3.3.2). The additional manipulations carried out specifically for each design are now described.

Design 1: footprint

The 'footprint' was defined as the design that provides the most plantar XYZ points of the foot during ground contact. It is called 'footprint' because of its similarity to a footprint in the sand. The data for this design was generated using software developed by the Biomechanics Research Group at Tuebingen University. There was no additional manipulation performed by the author. The reason for this design was to allow minimum support of the foot, as this footprint would provide a 'loose fit' in contrast with the static design.

Design 2: dynamic

The 'dynamic' design combined the point cloud data from different phases of ground contact (based on the longitudinal study in this thesis and the data from Schmeltzpfenning *et al.* (2010)), making this the most complex design. For this, the foot was divided into three regions: heel, midfoot and forefoot. The background for this insole design is to take the most functional frames during ground contact for each foot region: heel during initial contact, midfoot during supporting phase and forefoot during propulsion. The data selected for the heel was the point of heel strike, before the full lateral expansion of the fat pad, to allow a similar heel cup support to the one experienced in the longitudinal study. The point cloud data from the midfoot was taken at 50% of the midstance phase (MSP). This frame represents the supporting phase during the roll over process and it was selected to allow the natural movement of the arch (arch collapse). The longitudinal study presented in this thesis suggests that a higher arch design could be uncomfortable. Finally, the data selected for the forefoot was during terminal stance phase when heel was clearly lifted and this region had maximum weight bearing and widest value (Schmeltzpfenning et al., 2010) (Figure 6.3). After selecting the data, the 3 files were combined using the option 'merge polygon objects' from Geomagic Studio, which creates a single polygon object from two or more active polygon objects.

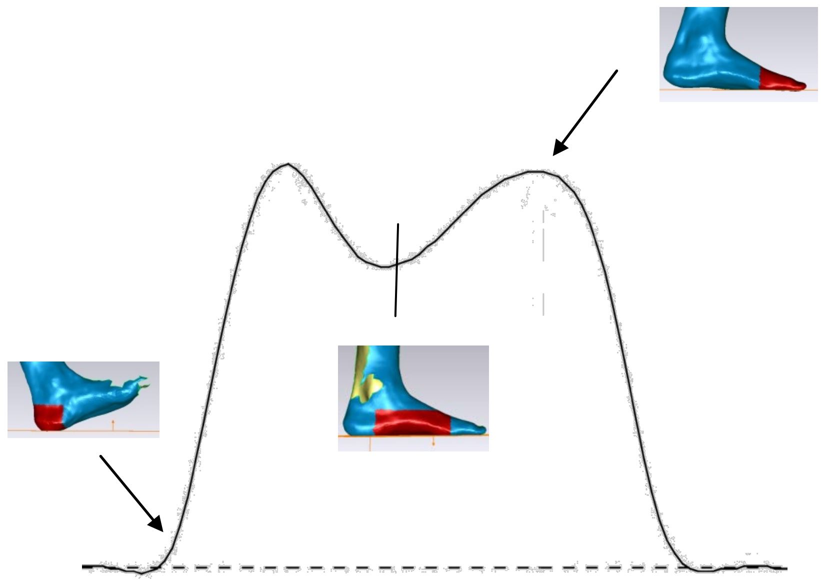


Figure 6.3. Example of the data selected for the dynamic design. Regions in red correspond to the area selected to combine the 3 files; the graph represents the vertical ground reaction force during walking.

Design 3: average

The 'average' design consisted of: (1) identifying the moments of foot flattening (the entire foot on the ground) and the start of heel rise, which defines the MSP, and (2) averaging all the point cloud data (between 5 and 10 frames) contained in this MSP, using the function 'average polygon objects' on Geomagic Studio (Figure 6.4). According to the manual, this function creates a new object that is the average of two or more original objects (5-10 frames in this case). This design was included because during the MSP the foot experiences the highest loads.

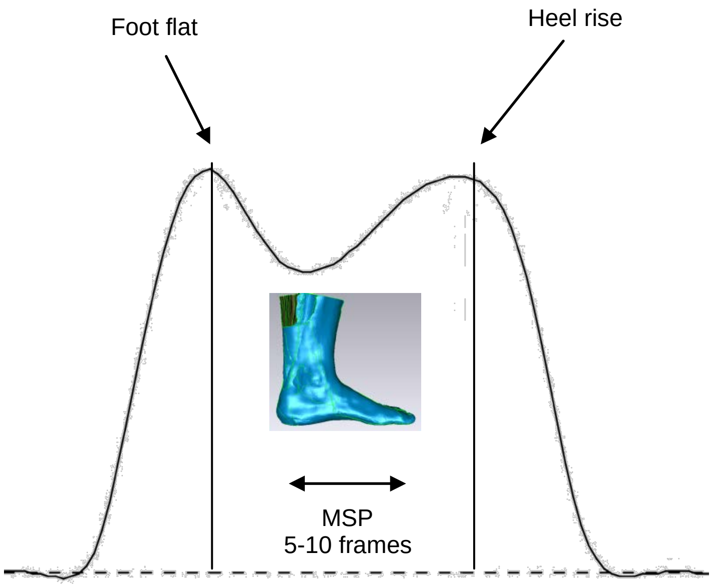


Figure 6.4. Example of how the point cloud data was identified and selected for the average design. The graph represents the vertical ground reaction force during walking.

Design 4: static

Finally, the last design was considered as a ‘static’ because it involved capturing the foot statically, following a similar protocol for foot capture and insole design to the longitudinal study (Chapter 5). This design was included to serve as a base for comparison in terms of the process and comfort assessment.

6.3. Results

Characteristics of the four participants (2 males and 2 females) are shown in Table 6.1. In this section, observations regarding the footwear personalisation process will be presented first, followed by the comfort rankings.

Table 6.1. Descriptive characteristics of the participants.

Participant number	1	2	3	4
Gender	Male	Female	Male	Female
Age (yrs)	31	32	34	29
Height (cm)	181	168	187	167
Body mass (kg)	77	66	79	55
Shoe size (UK)	10	7	10	7

6.3.1. The personalisation process

In general, the scan data showed good resolution (not much 'noise' was detected) and Geomagic Studio was suitable for the process. As reported earlier, this scanner generates approximately 36 point clouds. The time to scan was less than a second per foot, although the participants needing to walk on the 4.6 metre walkway took around 4 seconds. There were 2 main limitations of the scanner. First was that a shadow formed when the unscanned leg was swinging, obstructing the view of the lateral cameras. This is exemplified in Figure 6.5, where the area in yellow (frames 6 and 7) represents this shadow. Another limitation was with regard to the quality of the data at the moments of heel approaching the ground and the toe off position, which did not fully capture the foot (frames 1 and 12 in Figure 6.5).

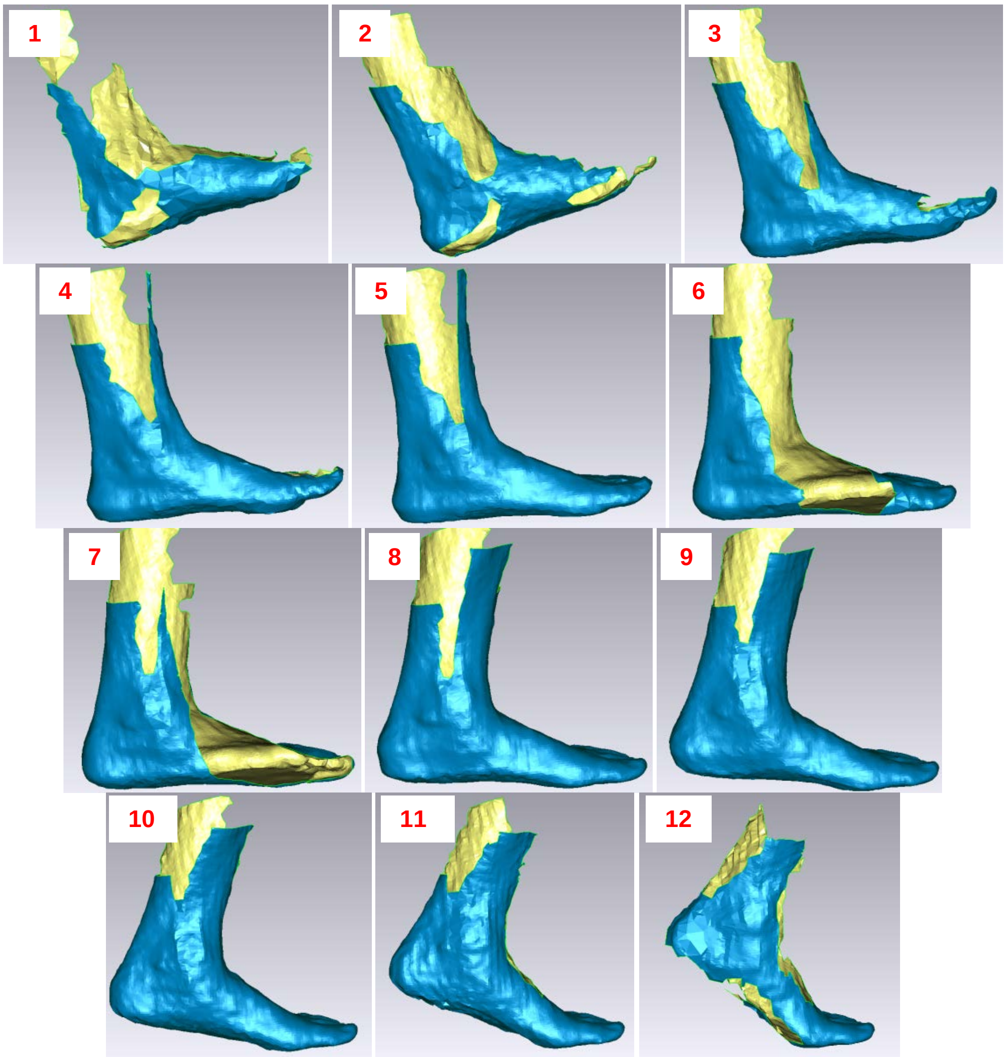


Figure 6.5. Screenshot showing a sequence of triangulated data collected with the dynamic scanner during the ground contact.

In the design phase, any gaps in the data were easily corrected using the automatic filling option of the software. The toe region of the dynamic, average and static designs proved to be the most complex to manipulate. The reason for this was that 4 mm was the height of the forefoot area and this region of the foot has curvature in the phalanges, so that the whole curved area needed to be deleted and reconstructed using the automatic filling option of the software to provide a smooth and flat appearance. The curvature in the forefoot region is shown in Figure 6.6.

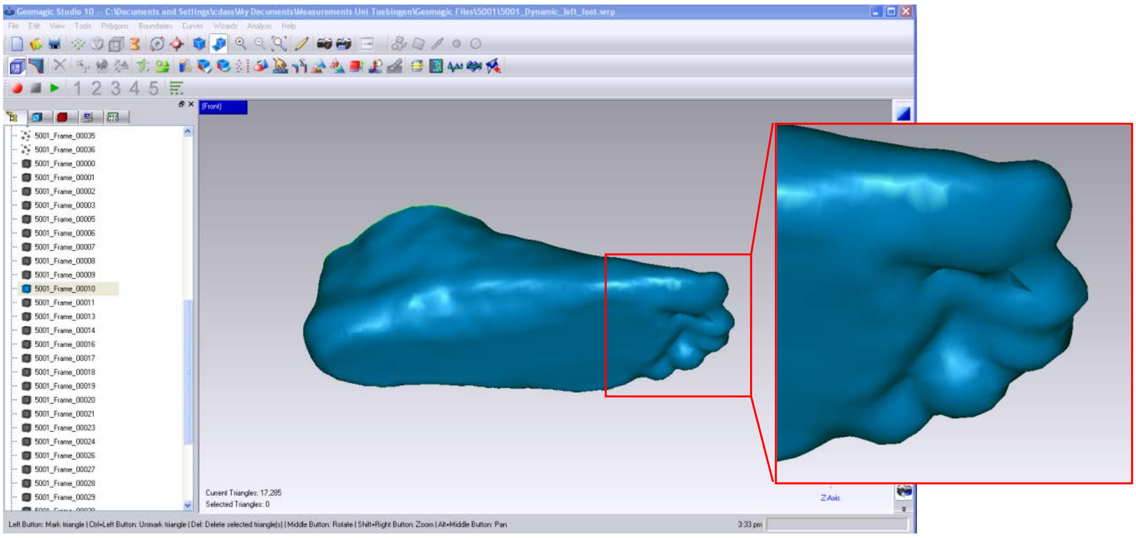


Figure 6.6. Screenshot showing the curvature in the forefoot region.

Each design had its own particularities and challenges. The 'footprint' data proved to have a very low resolution, with few points in the point cloud, making each triangle too large (Figure 6.7), demanding the use of the option "refine 4X subdivision" of the software, which subdivides every triangle into 4, multiplying the total number of triangles by 4. By increasing the number of triangles, more accurate shapes could be generated, allowing a smaller number of triangles to be selected in a region, giving the data a smoother appearance. Finally, the footprint insoles were also longer and wider than the other designs and it did not fit one participant's shoes. This insole was not included in the comfort perception for this person. This was the quickest insole to design (1 hour per pair) because there was less need to delete data. Also, it was not possible to have the stipulated 15 mm height for the heel cup and 4 mm in the forefoot, because this data provided mostly the plantar contour of the footprint (Figure 6.7) and not the entire foot as used for the other designs.

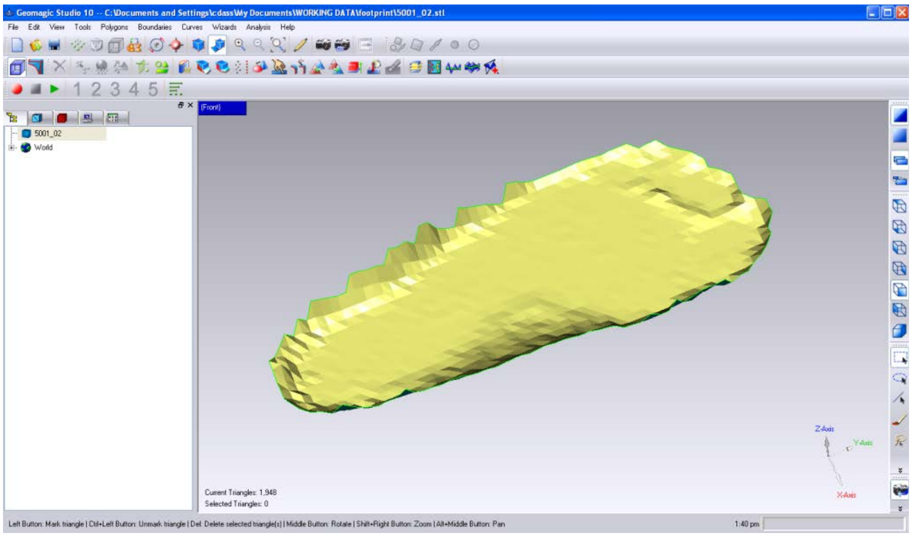


Figure 6.7. Screenshot of a raw triangulated footprint data on Geomagic Studio software.

The dynamic design was the most time consuming (3 hours per pair) due to the need to accurately select each region of the foot from different point cloud data, align and combine them in a way that it became one smooth part. Because during heel strike the heel is not flat on the floor, heel data had a different orientation in comparison to the midfoot and forefoot. This, together with the fact that the heel data had the smallest width, whereas the midfoot and forefoot had the widest values, meant that the 'align to plane' option was required from the software as well as 'create bridges' to join the different data.

Manipulation of the data for the average and static designs were very similar and only differed as the average included the identification of the MSP and the use of 'average polygon objects' function on Geomagic Studio. The former took 2 hours per pair to design, whereas the latter took 1.5 hours per pair. Figure 6.8 shows the insoles developed in the study and it can be seen that they were very similar in appearance.

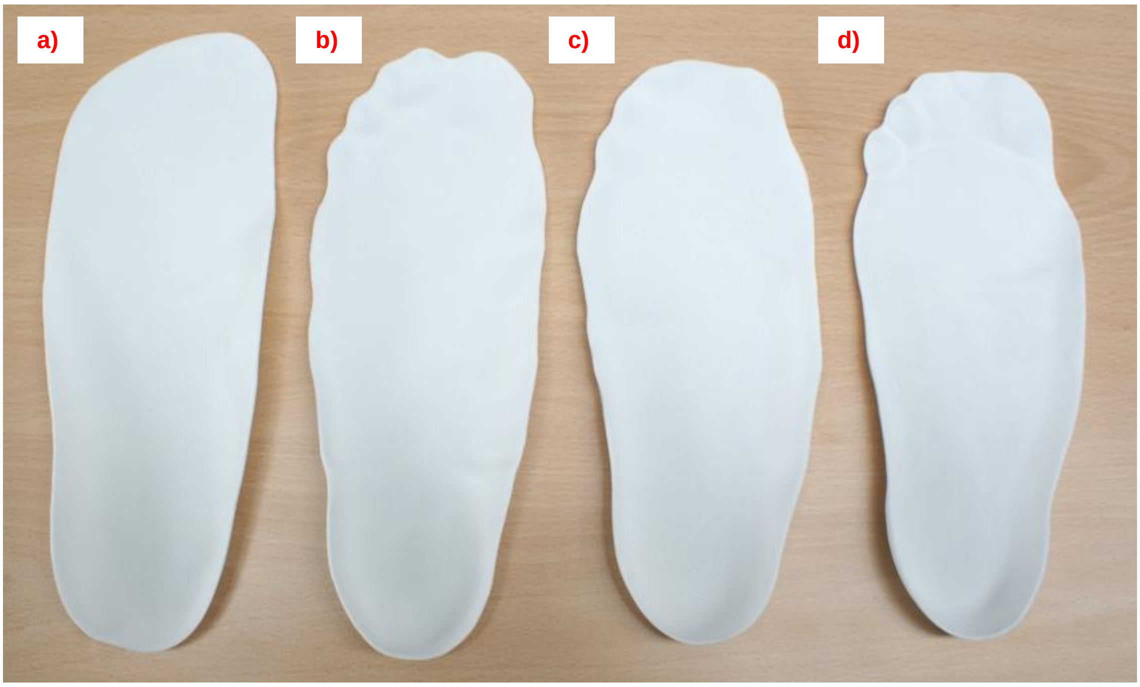


Figure 6.8. Top view of the insoles developed in this study. a) footprint; b) dynamic; c) average; d) static.

6.3.2. Comfort

The results of the comfort assessment are shown in Table 6.2. The numbers indicate how a particular design was ranked (e.g. 1 = most comfortable design; 4 = least comfortable). If two or more insoles had the same comfort perception by a participant, they were given the same rank. It can be seen in Table 6.2 that participants differed with regard to their preferences, but the dynamic and average designs were in general higher ranked for the heel and midfoot comfort. For the forefoot comfort, the footprint was better ranked, but it is important to mention that this design did not fit the shoe of one participant, so comfort was not assessed.

Table 6.2. Participants' insole preferences for each foot region.

Design	Region	Participant			
		1	2	3	4
Footprint	Heel	3	n/a	4	4
	Midfoot	3	n/a	4	3
	Forefoot	2	n/a	1	1
Dynamic	Heel	1	1	1	1
	Midfoot	1	1	1	2
	Forefoot	3	3	3	2
Average	Heel	4	1	1	1
	Midfoot	2	2	1	1
	Forefoot	1	2	3	4
Static	Heel	2	1	1	3
	Midfoot	4	3	3	4
	Forefoot	4	3	2	2

'n/a' means that the footprint insole was not tested as it did not fit in the shoe.

6.4. Discussion

The main aim of this study was to explore capturing the foot using a dynamic scanner for the design and manufacture of insoles using AM. While traditional footwear is based on the measurements taken in a static situation, according to Bibb *et al.* (2000), when scanning the human body it is important to consider the position and posture of the individual to ensure that the final part relates to the intended use. Although footwear should take into account both foot mobility and function to provide optimum fit and the number of dynamic scanners available has increased (e.g. Jezersek *et al*., 2011; Mochimaru and Kouchi, 2011), to the knowledge of the author there are no studies reporting the use of dynamic scanning for footwear development using AM techniques.

The scanner proved to be reliable in terms of capturing the foot with its data compatible with the entire process. In this study, the feet were captured during walking because the system scans at a maximum of 46 frames per second. This frequency is acceptable for walking trials, but it is definitely too slow for running conditions. Running exposes the skeletal system to much higher stresses than walking, especially when the foot collides with the ground (Bramble and Lieberman, 2004), so that any insoles developed for walking may not appropriate for running. Mochimaru and Kouchi (2011) introduced equipment capable of scanning at a higher frequency (200 Hz), producing around 100 frames for walking and 50 frames for running, but this is limited to the plantar aspect of the foot, posing difficulties in terms of whole foot measurement and footwear design. However, there has been considerable progress in the technical feasibility of capturing three-dimensional dynamic objects not only with the methodology of structured light and pattern projection, but also with time of flight systems and stereo vision technology. This provides promising perspectives from the shoe and insole construction, to the entire clothing industry, especially where fitting increases the functionality of the product.

In terms of insole design, the biggest challenge was the toe region. Because of curvature in the phalanges, this area of the scan had to be deleted and the gaps filled using the automatic filling option of the software. This is similar to Bibb *et al.* (2000), who used surface creation software to create a patch that corrects for areas obscured by the eyebrows, allowing the natural curvature of the surrounding data. Despite efforts to make a smooth surface, the 2 mm thickness and the hardness of the material (the same as used in the longitudinal study) gave all the insoles a ‘too hard’ sensation in the forefoot. This region needs a flexible material which compresses with the increase in pressure at late stance to give a feeling of comfort. The material used in this experiment was Nylon 12 in order to be consistent with the studies presented in this thesis. Although this material has shown very good durability for the short and medium term use (Chapter 5), further research is needed on AM materials to offer optimum comfort and function to the wearer.

The 4 different designs (footprint, dynamic, average and static) produced distinct shapes for the heel, midfoot and forefoot. The 'footprint' design produced the widest and longest values for all regions and for this reason it did not fit the shoe of one participant, suggesting that footwear developed using this method may feel loose. On the other hand, the static design produced the narrowest dimensions which according to the longitudinal study may not be ideal for the midfoot region, although it showed good results in terms of heel cup discomfort. It has been suggested that the soft tissue over the rearfoot region is already fully deformed with 50% of the weight on one foot (Tsung *et al*., 2003) and that no significant changes would be detected with more load. Therefore, the ideal data for the heel region may be when it is less than 50% weight bearing.

Capturing the arch is not as simple as applying the same load experienced during walking to the static foot: evidence shows that the arch does not collapse as much during walking in comparison to static weight bearing circumstances, indicating that activation of the muscles during walking influences the shape of the soft tissue and arch structure behaviour (Schmeltzpfenning *et al*., 2010). Therefore, even though dynamic scanning systems are still complex and expensive, they can provide insights into foot function and dimensions under different loading conditions and during natural movements, such as foot walking.

Although the comfort assessment was only based on 4 participants, they had preferences in terms of insoles for the different foot regions, but the dynamic and average designs were better ranked in general. It is interesting to note that the participants reported difficulty in ranking the heel region and the results suggest that all of the designs were similar for heel comfort apart from the footprint, which was ranked lower (Table 6.2). This can be explained by the fact that the heel width values increase approximately 3 mm with the increase in weight on the foot (Houston *et al*., 2006), suggesting that this change is not enough to be detected by the participants. On the other hand, the footprint provides the most distal points in the heel region and any movement in the ankle when making contact with the ground (e.g. eversion) will increase its width. In the midfoot, the dynamic and average designs were better ranked than the footprint and static designs. This goes in accordance to the findings of the longitudinal study, when the arch height from the 10% weight bearing position was uncomfortable. Finally, for the forefoot region, the footprint design was better ranked, indicating that the 4 participants may prefer more space in this region to allow the lateral expansion of the soft tissues and toes. It must be acknowledged that if a design was considered the most comfortable, it only means that this design was the best between the options: it does not necessarily mean that the fit and comfort were ideal.

Witana *et al.* (2009) reported that the shape and cushioning properties of the supporting material of the midfoot has a direct influence on perceived feelings in this region. Also, as reported in the previous chapter, the arch of the foot is a spring structure capable of storing strain energy and returning it in an elastic recoil, making running more economical (Ker *et al*., 1987). Therefore, this region may require properties that allow the arch to act naturally and efficiently. However, these are just speculations and further research is needed to evaluate these insoles in terms of discomfort and biomechanics.

The main limitation of this study refers to the sample size and the participants themselves who were researchers with some knowledge of the process. This may have influenced the comfort assessments which may not be reliable. However, this is less likely to have influenced the exploration of the personalisation process itself using the dynamic scanner to capture the foot.

6.5. Conclusions

A case study exploring a novel approach for the development of personalised insoles using dynamic scanning and AM is presented. The process proved to be more complex and required additional time and skills than the insoles developed in Chapters 4 and 5. The main reason for this was that the point cloud(s) needed to be identified from a series of 36 frames and manipulated accordingly, presenting more challenges in the design phase. The data from this study has demonstrated that combining dynamic scanning and the AM technology is feasible for developing personalised insoles. The short comfort assessment, suggested that the 4 participants had different design preferences for each region. While traditional footwear/insole is based on static data, this study can be considered a starting point for the development of personalised insoles using dynamic scanning and AM.

Chapter 7: Discussion and conclusions

7.1. Introduction

This thesis has investigated and explored the specification of personalised footwear using AM technology. It has also evaluated such footwear in terms of comfort and health. For that, a literature review was first conducted to understand current knowledge in the area and to critically discuss some of the commonly used methods for evaluating footwear (Chapters 2 and 3). Then, a pilot study was conducted to explore the proposed personalisation process and try out the equipments, materials and techniques prior to a more in depth study (Chapter 4). Following this, a longitudinal study was conducted to evaluate the short and medium term use of personalised insoles in terms of discomfort and biomechanics and further help refine the personalisation process (Chapter 5). Finally, a case study was conducted in collaboration with the Biomechanics Research Group at Tuebingen University to explore the use of a dynamic scanner for foot capture in the design and manufacture of insoles (Chapter 6).

The specific findings of each study were discussed at the end of the respective chapters. Hence, this chapter will focus on a discussion of the research as a whole, how the studies relate to each other and help answer the objectives posed in Chapter 1. This chapter will also compare the findings with the literature, starting with the footwear personalisation process itself (3-D scanning, anthropometric measurements, insole design and AM), followed by some of the methodological considerations. Following that, a discussion of the commercial feasibility of the footwear personalisation is approached. This chapter ends with contributions to knowledge and suggestions for further research.

7.2. The personalisation process

In general, the findings of the research indicate that the footwear personalisation process using 3-D scanning, anthropometric measurements, CAD design and AM identified in Chapter 3 is feasible and can be used to deliver personalised footwear. The insoles developed as part of this thesis showed that the personalisation of footwear/insole geometry alone can provide benefits in terms of comfort and lower limb biomechanics (mainly through plantar pressure redistribution) in comparison to a generic type for the short and medium term use. Significantly lower discomfort ratings for the heel and fit were detected for the personalised condition (Chapter 5) and there was a trend for lower discomfort in the forefoot and midfoot. In terms of biomechanics, the personalised insoles resulted in less ankle dorsiflexion at foot strike, which could be related to the significantly lower heel pressure values and increase in plantar contact area. This is further confirmed by cases reported in the literature using a similar methodology to deliver insoles (Sun *et al*., 2009; Pallari *et al*., 2010; Saleh and Dalgarno, 2010). In terms of producing footwear using AM, only one study was found by the author (Van Der Zande *et al*., 2010), which produced ladies shoes following a similar process of scanning, designing and manufacturing using laser sintering (LS) and Nylon 12. However, their study focused on the methodology only and no human testing was conducted. This section will approach the personalisation process and will discuss the findings from each element with the literature.

7.2.1. Foot capture

7.2.1.1. 3-D scanning

Generally speaking, the research indicates that most 3-D scanners will be compatible with the personalisation process, leaving the focus of this equipment on other variables such as: resolution and accuracy, scanning time and the foot position required by the scanner. Resolution and accuracy will allow a trustworthy representation of the shape and dimensions of the foot. The pilot study showed that a relatively poor resolution can produce 'noise', demanding time consuming processing of the data and potentially altering some of its original geometry. On the other hand, the longitudinal study showed that a better resolution may increase the scanning time.

Scanning time of the foot is related not only to the resolution, but it can also be dictated by the foot position. Although this was not an issue in the longitudinal study as the participants rested the foot on the scanner, the pilot study required them to maintain ankle dorsiflexion, to make the foot parallel to the glass of the scanner and to stay still to permit the capture of the plantar aspect in a non-weight bearing position. As advised by Bibb (2006), any movement during data acquisition will lead to poor quality data. Therefore, in the case of the pilot study, a higher resolution could lead to participant fatigue and a struggle to remain still. A possible solution reported in the literature is the use of a support (e.g. Bibb *et al*., 2000; Sun *et al*., 2009) for the scanned limb. However, in case of the foot, although a support could help minimise movement, it would be difficult to assist with ankle dorsiflexion without making contact with the foot and obstructing the view of the scanner.

The foot position required or allowed by the scanner may be the most important variable to consider when selecting scanning equipment. The lack of consensus in the literature regarding the optimal foot position because of the resulting differences in foot dimensions and increase in contact area with increased weight bearing (Tsung *et al*., 2003) has been already extensively discussed in Chapter 3. However, the findings of the 3 trials provide additional and relevant information in this regard. The studies captured the foot in distinct ways: (1) non weight bearing and capturing only the plantar surface (Chapter 4), (2) 10% of weight bearing (Chapter 5) and (3) dynamic during walking (Chapter 6). It can be considered that the first showed good results because no significant differences in discomfort ratings or biomechanical variables were detected when personalised insoles were compared to those commercialised with the trainers. The insoles from the second foot position proved to be beneficial by leading to less reported discomfort and improving the biomechanical parameters when the personalised insoles were compared to a generic shape in short and medium term use. Despite the fact that there are significant differences in foot shape using these two methods, the results may indicate that, in general, a personalised insole is better in terms of discomfort and biomechanics (plantar pressure distribution and ankle eversion) than a generic type regardless the foot scanning position. However, if the aim is to provide optimum comfort and biomechanics, further research is still needed to compare the foot scanning positions. Some may argue that the amount of weight bearing for foot capture should be decided by a specialist depending on each individual case, like Pallari *et al.* (2010) did in a research that developed orthoses for rheumatoid arthritis suffers. It would, however, still be interesting to quantify and structure the specialist assessment to judge the ideal foot scanning position, so that it could be standardised and performed consistently by any individual after some practice.

In addition, the findings of the research indicate additional challenges which have not been considered previously when selecting the scanner: the implications for footwear design. Equipment that only captures the plantar surface of the foot (Chapter 4) does not allow the design of the entire shoe. However, they may enable the development of ¾ insoles. Although it is possible to use single camera units to take several scans and align the data using software to produce a single point cloud (Bibb *et al*., 2006), it requires planning, experience and software knowledge. There is also the possibility of involuntary movement between individual scans that can lead to error. Besides, this would be difficult to perform in dynamic scanning, for example, using a system like Mochimaru and Kouchi (2011) which captures the plantar aspect dynamically, as it would require the individual walking/running almost identically several times. Capturing the whole foot statically (Chapter 5) requires extra manipulation of the data, such as the design of heel cup and height delimitations. Although the scanner used in this study captured data sequentially, the time delay between the four individual scans was very short and in practice, involuntary movement did not pose a problem. The resolution and accuracy of the resulting data proved more than adequate for the production of personalised insoles. The case study (Chapter 6) indicated that, with dynamic scanning, the main challenges are on the selection/combination of the point cloud data. The 36 frames generated by this scanner allow the design and development of multiple types of insoles, but the way 'designs' are optimised has yet to be identified. Although some researchers capture the foot in a full weight bearing as it will be closer to its shape during running (Cavanagh, 1980), capturing the foot may not as simple as applying the same load experienced during motion in the static foot as the there are differences in foot shape, especially arch structure behaviour, which can be due to the activation of the muscles and ligaments during walking (Schmeltzpfenning *et al*., 2010). Therefore, when selecting the scanner for the personalisation process it is not only important to consider the impact of foot positioning on discomfort and biomechanics, but also on the design phase and point cloud data selection. Moreover, if the scanner has to be placed outside the laboratory setting (i.e. in the field), it can present challenges, such as direct sunlight interfering the operation of the scanning laser, increasing scan 'noise' (Ball, 2011). Although static foot capture has been used in the vast majority of the cases in the literature, the use of dynamic scanning for insole or footwear development seems to have not been explored or at least not published.

In addition to the points discussed in Chapter 3, the selection of the scanner for the personalisation process has to consider its resolution, accuracy, scanning time and foot position, with the latter being the most important. The challenges go beyond static foot scanning and foot positioning, but include potential difficulties in the design phase and selection of the point cloud data generated if a dynamic scanner is used. The findings of this thesis indicate that an insole with personalised geometry produces better outcomes than one of a generic shape, but further research is still needed to compare current solutions for foot capture and to test insoles developed using dynamic scanning in terms of discomfort and biomechanics.

7.2.1.2. Anthropometric measurements

In this thesis, the anthropometric measurements were taken manually because the scanner used in the pilot study did not allow whole foot capture and also to follow the methods established in the literature (Chapters 2 and 3). However, given the 15 minutes needed for a relatively experienced researcher to take the 15 measurements manually (Chapter 5), it may be wiser to put markers on the foot and scan it, requiring about 6 minutes per foot (2 minutes for marking the foot, 3 minutes for positioning and 1 minute for scanning). Extracting these measurements electronically can then be done later without the need for the individual to be present in the shop/laboratory. However, the results the majority of the anthropometric measurements taken for this research were not necessary for footwear personalisation and this will be discussed below.

The research suggests that for the personalisation process, the most useful measurements for the specification of the three quarter insoles are the length of the foot from the heel to the first and fifth MPJs, which were used to indicate their end points (see Chapters 4 and 5). In the case of footwear, these can help determine the flex point of the shoe. In addition, navicular height proved to be useful by indicating the height of the arch region if the whole foot is captured. The other 12 measurements were not used in the design of the insole itself.

Probably the most surprising results are the correlations between the anthropometric measurements and the discomfort and biomechanical variables. Significant correlations were only detected in the pilot study and therefore may not be reliable: relative arch deformation (RAD), metatarsophalangeal joint (MPJ) height and hallux height correlated positively with discomfort ratings. From the literature, it was expected that calculations concerning the medial longitudinal arch (RAD, arch index and arch ratio) could indicate comfort, supporting properties and individual preferences. None of these 'calculations' correlated with the discomfort or biomechanical variables in the longitudinal trial. There are potential explanations for these findings. As reported in Chapter 5, the 10% weight bearing used by Nigg *et al.* (1998) and Williams and McClay (2000) as part of the RAD calculation may not represent arch stiffness accurately as with this level of weight bearing, some structural and dimensional changes will have already occurred in the arch. Mundermann *et al.* (2001), in a study of 206 military personnel, found that people with a low arch (LA) foot tended to prefer harder insoles, whereas high arched (HA) individuals tended to choose softer ones. In addition, the literature shows that arch morphology can provide information with regard to function and the potential risk for the development of injuries. High arch individuals have been associated with receiving greater shock from the ground, whereas low arched people have high values for rearfoot eversion. Thus, cushioning training and motion control can help to provide the necessary support and cushioning for the reduction of injury risk in running (Butler *et al*., 2006 and 2007). Although Mundermann *et al.* (2001) did not report the methodology used to determine high/low arched individuals, the studies from Butler and colleagues used the same arch ratio calculation as this thesis (which they referred to as ‘arch height index’). One potential explanation for the findings of the longitudinal study is the lack of correlations between arch height, discomfort and biomechanical variables in individuals with a normal arch. There may be relationships between these variables for the high and low arched foot, but a linear decrease in arch height with increased comfort or biomechanical parameters may not exist. Butler *et al.* (2006) and (2007) recruited only high and low arched runners, whereas the individuals involved in the studies reported in this thesis consisted predominately of those with normal arches. Also, another study showed that selecting running shoes based on static analysis of plantar shape (i.e. high and low arches) did not reduce the risk of injury (Knapik *et al*., 2009). Therefore, the effectiveness of ‘correcting’ the foot has to be questioned as there are runners with a severe flat foot, together with their long medial longitudinal arch completely collapsed, who function without problems and are managing very well (Cavanagh, 1980). So, in terms of personalised footwear, there may still be some potential for using arch calculations: further actions in terms of footwear specification would only be conducted if the individual was high or low arched. However, the results from this thesis do not support such conclusions and these are mere speculations. Possible correlations between low and high arched runners and discomfort and biomechanical variables using personalised insoles need to be further investigated.

In summary, from the 15 anthropometric measurements taken, only 3 were directly used in the design of the insole/footwear: the length of the foot from the heel to the first and fifth MPJs and navicular height. No measurements correlated with the discomfort or biomechanical variables in the longitudinal study, indicating that taking all 15 dimensions may not be necessary. Although the ‘arch calculations’ (RAD, arch index and arch ratio) also did not correlate with any of the discomfort or biomechanical variables, they may still be useful to specify the footwear if the individual is high or low arched, but this needs further investigation.

7.2.2. Additive manufacturing technology

In terms of AM, it is important to clarify from the beginning that research conducted in this thesis only explored the manufacture of insoles through LS and using Nylon 12. As explained in Chapter 3 (Section 3.2.2), the development of the entire functional footwear using AM is currently not viable and is being investigated by the other research packages in the Elite to High Street (E2HS) project. Hence, this section will discuss AM in terms of producing personalised insoles and will provide initial guidance for footwear generally, but the author anticipates that further challenges may be encountered for complete shoe development.

The research has indicated that manufacturing personalised insoles via AM is feasible and is more straight forward than the other elements of the process (foot scanning and insole design). This may be due to the simple design of these insoles, which did not incorporate any functional element (e.g. shock absorbing capability). The time of 28 hours estimated for the manufacture of 12 parts (6 pairs; Chapter 4) can be considered high if compared with the availability of off the shelf inserts, but it is acceptable if compared with customised products, like orthotics or prescription glasses. The main contribution of this thesis on the AM side is with regard to the short and medium term evaluation of the insoles made from LS and Nylon 12. Based on the research in this thesis and supported by successful cases (see Section 3.2.2), it is possible to conclude that AM is ready to fabricate personalised insoles and orthotics in terms of durability, comfort and biomechanics to the high street (Chapter 5), but its commercial feasibility needs further discussion (Section 7.4).

The main limitation with AM is the materials currently available. Nylon 12 was chosen in this thesis because it is widely known in the research community and is durable. Indeed, the longitudinal study has indicated very good durability after 3 months: none of the insoles showed signs of breaks or cracks in the visual inspection. Also, this material was useful in providing the sensation of heel stabilisation and good fit and improving mainly the plantar pressure distribution and ankle eversion. Although the hardness of the material, coupled with the personalised geometry, gave the positive sensation of heel stabilisation, this property may also be its main limitation, especially if used in the arch area of the foot. Therefore, the material may be suitable if the aim is to restrict the movement of the foot and provide support for individuals that require these features, but it is unclear whether this is really necessary for healthy individuals who find it ‘intrusive’ and unpleasant. As reported previously, shape, flexibility and cushioning properties of the supporting material will influence feelings of comfort and will dictate the amount of force that the foot will experience during ground contact (Chen *et al*., 1994; Lake, 2000; Witana *et al*., 2009). It has been reported that in a soft shoe there will be a higher deformation of the material, increasing the contact area during the roll over process in comparison to harder shoes (Henning *et al*., 1996). Thus, ideally the material of the shoe should be elastic to cushion impact with the ground and store energy, returning some of the mechanical work done to it (Alexander, 1987). Therefore, the current materials of the midsoles of running footwear are elastic, usually ethylene vinyl acetate (EVA) or polyurethane, which help shock absorption between the foot and the ground (McPoil, 2000). According to Shorten (1993), some of the work that is generated during the ground contact is stored as strain energy in the deformed material and some is dissipated as heat. As the load is released, the elastic material returns to its original shape (McPoil, 2000). According to Novacheck (1998), a good running shoe has to provide shock absorption and stabilisation. Therefore, in an ideal situation, AM could work with these EVA or polyurethane materials or with elastomer materials that show similar mechanical properties. According to Van Der Zande *et al.* (2010), another difference when designing shoes using conventional techniques is that the dimensions are compensated by the designer to take into account the deformability of the material (e.g. leather), but with the LS materials this cannot be done as they are 'non-deformable'.

The materials available for the LS equipment used in this study include: DuraFom® Flex, DuraFom® PS and DuraFom® EX (3D Systems, 2010a). Of these, perhaps DuraFom® Flex is the most appropriate alternative for the production of insole/footwear because it is 'a thermoplastic elastomer material with rubber-like flexibility and functionality' (3D Systems, 2010a), whereas the others use either glass or aluminium fillers. However, not only has its application for footwear development not been tested to a great extent, but also because it is flexible (Shore A 60), it would not provide the same heel cup support as the Nylon 12. Communication with another member of the E2HS project has also suggested that DuraForm® Flex may not last for medium term use (e.g. 3 months), making it much less durable than the DuraFom® PA (Nylon 12). According to Gornet (2006), another limitation of polyamide materials is that the surface finish can become very rough, affecting aesthetics qualities for some end products. The difficulty in finding a material that suits insole/footwear demands may be partially explained by how LS works. The technique preheats power material to just bellow melting point and a laser scans the cross-section, fusing the particles together (Bibb, 2006). Some materials are not well suited to this as it is difficult to achieve complete melt (Gornet, 2006). In terms of fashion footwear, Van Der Zande *et al.* (2010) reported that current CAD systems, material and production processes are not sufficiently developed to a state that the shoes manufactured using AM technologies are commercially viable. Once the material has been chosen, another critically important constraint is the weight of the shoe as any extra weight in the foot segment will increase rotational kinetic energy (Cavanagh, 1980), potentially decreasing performance and increasing fatigue. Also, the LS parts are porous, and therefore could promote sweat absorption, potentially leading to hygiene problems in the long run. Furthermore, the shoe should also take into consideration the surface the individual runs on. For example, if running on a trail, the shoe may require more durability and grip in comparison to road running, which in turn may require more shock attenuation in comparison to treadmill running. As it can be seen, it will not be as easy to select AM materials that have similar properties to the ones in traditional running shoes. The range of materials available for AM processes still requires investigation.

Although this PhD thesis has only investigated the use of the LS process, it would be interesting to explore and compare other AM techniques or even computer numerical controlled machining (CNC), in terms of time to manufacture, costs, quality of finish and materials. Saleh and Dalgarno (2010) reported a brief comparison between orthoses fabricated by LS and fused deposition modeling (FDM) and showed that they would be £20 cheaper if manufactured with LS. Another possibility is to use a 3-D printing process (e.g. Objet Connex 500) that is capable of producing insoles using more than one material in the same batch. This will be explored in Section 7.7.1. With regard to CNC, although computer based, it is not an AM process as it is more a subtractive than an additive process (Gibson *et al*., 2010). CNC may offer an interesting alternative because of the very wide range of materials available which include foam, as well as a variety of machine sizes and costs (Bibb, 2006). However, the author acknowledges that comparing manufacturing technologies is not simple. A great deal of factors must be considered, especially if used for commercial purposes and the findings of this thesis do not allow any conclusions in this respect.

In summary, AM is ready for the fabrication of personalised insoles in terms of delivering durable, comfortable insoles to the high street. However, the materials available are the main concern, especially in terms of providing comfort in the arch area. The materials and AM technologies need to be further investigated in terms of mechanical properties, materials available, time to manufacture, costs and quality of finish.

7.2.2.1. Insole design

During the course of this thesis, the insole design proved to be dependent on the 3-D scanner and the type of foot capture. As reported in Section 7.2.1.1, the challenges increase significantly if a dynamic scanner is used. The time required to design the insoles ranged from 1 hour (footprint design) to 3 hours per pair (dynamic design) in the case study (Chapter 6). This time is dependent on the designer's experience, but the data manipulation/design element of the process can be considered to be the most laborious, although not the most time consuming (Chapter 4). According to Tuck *et al.* (2008) and Gibson *et al.* (2010), the manufacturing of parts takes the majority of the time, but it is an automated process that requires little or even no operator involvement.

Despite the fact that the insoles were designed by the author who has limited expertise on reverse engineering software, the manipulation of the foot scan data potentially requires a CAD specialist if commercialised. Regardless of the person responsible for this stage of the process, it is important that the design procedures (e.g. amount of smoothing, noise reduction) are standardised as they will influence the final data (Tuck *et al*., 2008). Without standardisation, these operations will vary according to the designer (being designer-dependant) and an optimal design may not be achieved in all cases, although every product would still be unique.

Another factor to be considered in insole design is the CAD software needed to manipulate the scan data. Magics was chosen for the pilot study, but did not have all the necessary tools due to it being primarily for STL repair and build set-up: manual sanding was needed to remove all sharp edges (Chapter 4). As a consequence, Magics was replaced by Geomagic Studio, which allowed data and boundary smoothing, thickening, engraving and measurements to be taken to determine the 15 mm height of the insoles. However, Hague *et al.* (2003a) reported that current CAD systems have limitations that need to be overcome: these systems do not offer the same spontaneity of creative design and require extensive training due to their complexity, indicating that they still need some form of development. However, this may not be an issue that applies to footwear as the data manipulation is likely to be carried out by a specialist and the functionality and geometry of the shoe will constrain the amount of creative design, not tolerating as much of it as other products. Another limitation is that, although AM processes will enable the production of parts using different materials, CAD packages cannot represent them, except with very rough resolution or on small parts (Hague *et al*., 2003a). According to Gibson *et al.* (2010) the challenges for CAD software for AM applications are allowing:

- geometric complexity;
- physical material representation – material composition (carbon, steel) and distribution of mechanical properties (hardness) must be represented;
- physical property representation – the desired distribution of physical and mechanical properties must be represented.

As already reported, there are multiple CAD systems available on the market, such as: FreeForm (SensAble Technologies, Inc., USA), Geomagic Studio (Geomagic Inc., USA) or Magics CAD (Materialise Group, Belgium). However, few research studies report the actual advantages and limitations for each one specifically. For example, Eggbeer (2008) used FreeForm and reported that it was suitable for designing the shape of facial prostheses and digitally positioning, based on scan data from 4 case studies. This software allows the user to sculpt a virtual model and while doing this, he/she can 'feel' the model allowing a tactile sensation in addition to visual feedback (Hague *et al.*, 2003a). In the case of footwear/insole design it is still unclear whether this haptic feedback is an advantage or disadvantage, given that it would allow a 'feel' for the part, but this 'feel' would be 'designer-specific' instead of standardised. So, it may work very well for cases when the expertise or input of the designer is wanted, but less well in standardised systems. The company Delcam PLC (Birmingham, UK) offers a range of CAD software for the design of the shoe (ShoeDesign), midsole (SoleEngineer) and last (LastMaker). However, the author has not found any academic literature concerning use of any of these systems.

The findings of this thesis are more relevant to the actual insole design, rather than software. Apart from the features already listed in Chapter 3 (Section 3.2.2.1), this research has indicated that additional operations may be relevant. For example, it is essential to establish a way to label the AM parts to aid their identification, especially if this process is applied to a large scale. Engraving was used in the research and it was satisfactory as it did not affect the integrity of the parts. The longitudinal trial showed that the high arch profile of the inserts, coupled with a hard material, can give an unpleasant sensation. Hence, it was proposed in Chapter 5 that data could be manipulated to change the arch profile. If the researcher is constrained by a particular scanner and the way the foot needs to be captured, another important capability of the software is to be able manipulate the arch region, lifting or reducing the support. However, this has not been explored so it is unclear whether Geomagic Studio would be suitable. Further challenges in data manipulation were observed in the case study, in terms of reshaping the toes region. Due to the inexperience of the researcher, this problem was resolved by deleting the whole area and using the option 'fill gaps' from Geomagic Studio, but other options that do not require the deletion of the data may exist. In summary, additional requirements of the reverse engineering software were:

- engraving (or embossing) for the identification of the parts – used in all the 3 studies. This can be done outside the design phase and not necessarily using the same software;

- manipulation of the data especially the arch region in order to lift/reduce the height/support, depending on requirements – based on the findings of the longitudinal and case studies;
- measuring of the part so the exact delimitation can be performed (e.g. 15 mm height for the heel cup) – used in the longitudinal study;
- combining different point cloud data as one single part – this operation was necessary for the 'dynamic design' in the case study;
- changing the XYZ alignment of a triangulated surface – this operation was also necessary for the 'dynamic design' in the case study;
- subdivision of every triangle, multiplying the number of triangles to allow a better resolution – this operation was necessary for the 'footprint design' in the case study.

In case of footwear design, the literature provides some additional advice. For example, shoes should have 1 cm extra space between the end of the longest toe and the end of the shoe to allow some movement and provide a good fit (Janisse, 1992). Finally, it should be considered that the forefoot is where the forces are largest for runners, indicating that this region needs good grip and a way of providing protection.

In conclusion, the research in this thesis has shown that insole design is highly dependent on the designer's experience and can be considered the most laborious of the personalisation process. Ideally, the design procedures have to be standardised, otherwise it will be designer-dependant. In terms of CAD software, there are many alternatives on the market, but Geomagic Studio was confirmed to be appropriate for the operations required in this thesis. In addition to the features listed in Chapter 3, reverse engineering software should allow further data manipulation such as: engraving for the identification and measuring to specify its delimitations.

7.2.2.2. Specialist design

As reported in Chapter 3, any physical/biomechanical assessment would need to be conducted by a specialist (e.g. physiotherapist, podiatrist) who would advise on foot and gait abnormalities. Although specialist design was not explored, the experience gained throughout this thesis may contribute to further research and development.

The challenges would be on the quantification and standardisation of part of the professional assessments in relation to correcting for abnormalities (e.g. gait analysis).

Prescribing orthoses has been reported historically as being a trial-and-error assessment (Houston *et al*., 2006). Although these specialists may have common practices such as capturing the foot with subtalar joint in its neutral position, they differ in terms of diagnosis and intervention. This is evidenced by Guldemond *et al.* (2005), in a Dutch study which compared orthoses made by podiatrists, pedorthists and orthotists regarding plantar pressure reduction and found differences between specialists in terms of the insole construction and outcomes. This is also confirmed by Mr. Steve Avil from the University of Northampton (one of the 3 podiatrists consulted in this thesis), who said that he practices 'an art rather than a science'. This inconsistency between appraisals from one specialist to another may also explain why some individuals respond positively to orthoses and others do not. As stated previously, this clinical evaluation is optional and could be offered as a premium service for footwear personalisation. Including a specialist in the process is very likely to substantially increase the price of the footwear, given the reported cost for podiatrist service of between AUS$ 100-150 (approximately US$ 103-154 or € 76-114) per hour in Australia (Payne, 2007).

Crabtree *et al.* (2009) presented a methodology focused on the manufacture of biomechanical corrective devices (orthotics) for sports activities which was similar to the one explored in this thesis. They indicated that the stresses experienced by athletes of a particular sport may differ significantly for another sport, because of variations of factors, such as: playing surface, type of shoe used and so on. Although this study by Crabtree *et al.* (2009) reflects the need for biomechanical assessments, they were unclear about what 'comprehensive biomechanical evaluation' should be conducted, provided no guidance and made no contribution towards its standardisation. A step in this direction could start with a systematic review of the literature about the running injuries and their potential causes in order to identify, either from successful cases reported or interviews with podiatrists, the best interventions. For example, reported designs for orthotics include a metatarsal bar and metatarsal dome, which are suggested to be efficient in terms of pressure reduction and pain relief (Hodge *et al*., 1999, Pallari *et al*., 2010). The amount of impact attenuation also has the potential to be tuned to the individual. Impact shock parameters like mean loading rate is associated with tibial stress fractures in female runners (Milner *et al*., 2006). As mentioned in Chapter 3, an ongoing research project (which ends in 2013) named A-Footprint (www.afootprint.eu) is working to improve the accuracy of clinical prescriptions for orthoses, as well as their fit and functionality. It is expected that this project will contribute not only to the various elements of the process reported in this thesis (foot scanning, orthotics design and AM), but also to the specialist design which has not been explored in detail yet. An alternative for these specialist assessments is to offer some degree of pronation control similarly to the 'motion control' shoes currently on the market. For instance, the individual could have the foot measured and if his/her pronation was within a range which does not require clinical intervention, the personalised support would be supplied. However, this requires further investigation.

Finally, this specialist footwear design could be performed using the same software as in the longitudinal study or even specialised software for the manipulation of scan data for the generation of orthotics, for example: Orthomodel from Delcam PLC, Birmingham, UK; and Automated Orthotic Manufacturing System, Sharp Shape, USA (Telfer and Woodburn, 2010).

In summary, although the orthotic design involving a specialist has not been explored in this thesis, there is potential for further research in this area, especially on the understanding and standardisation of part of the clinical lower limb assessments. In this case, there is software available for the design of orthoses via reverse engineering. This element could be offered as a premium service and could benefit mainly the individuals that require orthotics (e.g. rheumatoid arthritis or diabetes suffers).

7.3. Methodological considerations

This thesis has explored a process to enable the specification of personalised footwear for AM. Although the process has been reported and explored in detail, one has to bear in mind that technology changes rapidly, so there is potential for changes in the near future with regard to scanning techniques, CAD systems, AM processes and materials. Also, this research was often compared and discussed with the literature specialised in 'medical' orthotics because personalised footwear using AM is a novel area, with little scientific evidence. Therefore, it must be acknowledged that orthotics and personalised insoles are different markets with different requirements. Unfortunately within the scope of this thesis, other materials, processes and designs could not be explored. The AM element of the process was mainly guided by the Additive Manufacturing Research Group at Loughborough University as part of the whole E2HS project. Hence, the researcher had no control over the settings and parameters for the fabrication of the insoles. The overall research was driven by the literature, talks with podiatrists, the E2HS team and time and costs constraints.

This thesis claims that insoles manufactured following the personalisation process can provide benefits in terms of discomfort for the short and medium term use and lower limb biomechanics in comparison to a generic type. The results presented may be pertinent solely to the methodology used (e.g. sample, insole hardness) and to the development of running shoes, while other types of sports shoes may require different properties depending on the movements involved (e.g. cutting, stopping, landing and rotating manoeuvres). Even for walking conditions the results have to be interpreted with caution.

The differences in study design were a consequence of different aims and, more importantly, of a learning process. For instance, in the pilot study the control condition consisted of the insoles that came with the shoes, as the main objective of that study was to explore and refine the research methods and the personalisation process. Also, the pilot study exposed the difficulty of booking the research laboratory for 2 consecutive days, which resulted in removing the running economy test from the assessment methods as it would be impractical for the longitudinal study with a much bigger sample size. Having said this, running economy can still provide relevant data about the effect of the insoles on runners and there is potential for further research to be conducted in this regard. The thermal sensation assessment was also removed from the methods as a result of the pilot study, because materials and geometry of the insoles did not contribute significantly to changes in thermal sensation in the laboratory sessions. In the longitudinal study, the VAS was suitable in the field and discomfort was prioritised over thermal sensation in order not to burden participants with too many scales. However, the thermal sensation evaluation may still be valid when assessing the long term use.

Another difference between the pilot and longitudinal studies was the foot scanning position. In the pilot study, the type of scanner used restricted options for foot posture, so it was captured in a non-weight bearing condition. In the longitudinal trial it allowed the participants to be seated, maintaining a 90° ankle joint, with the lower leg perpendicular to the glass of the scanner and applying 10% of weight bearing in the foot (Laughton *et al*. 2002). Furthermore, in both studies the subtalar joint was not controlled to its neutral position during scanning as is common practice between podiatrists. However, this has been questioned in terms of being based on a misinterpretation of the literature (Miller and McGuire, 2000) and for this thesis would require specialist help, which was not possible. Finally, the case study scanned the foot while in motion as suggested in the literature and by podiatrists who also indicate that a dynamic assessment may be the best option for footwear development.

In terms of the anthropometric measurements of the foot, these were taken manually because the scanner used in the pilot study did not allow whole foot capture and the ability to follow the approach established in the literature. However, it may be better to extract dimensions from foot scans using software and anatomical landmarks, without the need of the runner to be present. In addition, the measurements were taken in bipedal standing (i.e. the weight equally distributed in both feet) in an attempt to standardise with the literature, but, as reported in Chapter 3, the literature is inconsistent with the amount of weight bearing when measuring the foot. Therefore, the correlation analysis between the anthropometric measurements and discomfort and biomechanical variables conducted in Chapters 4 and 5 could have presented slightly different results if the measurements were taken adopting a different position.

Another important consideration is that the results were presented and treated as ‘mean’ values between conditions. However, individuals have different responses to inserts and an identical intervention can produce substantially different results between subjects, because they are influenced by mechanical, neuro-physiological, anatomical and even psychological attributes (Dixon *et al*., 2000; Nigg *et al*., 2003). Therefore, identifying the best insoles may not be as simple as comparing the mean values. More important it is to identify a method which would be the best for 95% or 98% of the population. In other words, there will not be an insole design that is comfortable and biomechanically ideal for everyone, but the best attempt is to include as many individuals as possible, even if in the future the individual has to try out a range of personalised insoles with different design and material combinations. However, research into whether a series of inserts is needed rather than one type has to be conducted.

In terms of biomechanics, the longitudinal study showed that individuals in the personalised condition showed less ankle dorsiflexion at foot strike (FS). According to Lieberman *et al.* (2010), landing on the heels (and higher ankle dorsiflexion at FS) is a common characteristic of shod individuals because of the cushioned sole of running shoes. This is thickest below the heel orientating the sole of the foot to have about 5° less dorsiflexion than the sole of the shoe. However, it is unlikely that the shoes and thickness of both insoles contributed to the ankle dorsiflexion as the shoes were the same and the insoles had a similar thickness (2 mm).

The findings of the longitudinal study have indicated that the arch height of the insoles may not be ideal because it was potentially restricting natural movement. This is confirmed by Alexander (1987), who reported that the arch support of trainers opposes the flattening mechanism involved in the spring action of arch and hinder runners instead of helping them. These arch supports have also been speculated to be prejudicial to weaker foot muscles, reducing arch strength, contributing for excessive pronation (Lieberman *et al*., 2010). Therefore, it would be interesting to evaluate if the alternatives proposed in Chapter 5 of allowing the arch to collapse during running would have an effect on the biomechanical parameters, like ankle dorsiflexion, maximum eversion and plantar pressure. If this is the case, the footwear developed would have to choose between improved comfort or improved biomechanics.

The pilot study provided an opportunity to explore and try out the equipment, materials and techniques, so it was expected that any potential problems could be anticipated. However, this did not turn out to be the case for the plantar pressure measurements, as it did not detect the need to adopt systematic replacement of the sensors. The reason was that the participants wore different trainer sizes, so that different (and new) sensors had to be used for all of them. However, the author believes that the plantar pressure results from the 'month 0' session of the longitudinal study was reliable, as the peak pressures and mean contact areas had similarities with the literature and with the pilot study. Sun *et al.* (2009), reported that 'glove fit' insoles lead to a reduction in heel and forefoot pressures, while the midfoot pressure and foot contact area increased. In addition, full conforming insoles with a heel cup (similar to the ones used in the longitudinal trial) are also reported to provide the greatest reduction in peak pressures under the heel region in comparison to a barefoot condition and this is suggested to be due to the load being distributed over a larger area (Goske *et al*., 2006).

7.4. Commercial feasibility

As reported in Chapter 1, this thesis is part of a larger 'Innovative Manufacturing and Construction Research Centre' funded research project (Elite to High Street – E2HS) which aims to develop high performance personalised sports footwear using AM and enable affordable fully personalised sports footwear to be available for high street individuals. Therefore, it is important to interpret the findings in the context of commercial feasibility. Some of the potential benefits and limitations of the personalisation process have been mentioned in Chapters 2 and 3. Therefore, this section will discuss the literature and market with regard to what is currently available and feasible, rather than theoretical future possibilities. As reported extensively in this thesis, AM is not ready to produce the entire shoe/footwear yet, but advances are being made by the Additive Manufacturing Research Group at Loughborough University on the development of functional midsoles. Therefore, the current state of art is that personalised insoles would be incorporated into standard AM midsoles; the upper and outsole (and lacing) would have to be assembled using conventional techniques. This research is aligned with the in-store concept being developed in the E2HS project (Head and Porter, 2011), but will only consider what has been explored in this thesis and will start with the potential benefits and disadvantages without the constraint of cost.

7.4.1. Potential benefits

This thesis has shown that the personalisation process can deliver insoles that can reduce discomfort, mainly by providing better fit and stabilisation sensation over short and medium term use. Optimum fit is probably the most important property that will benefit a greater number of individuals using such an insole or footwear. In a study with 235 individuals from clinics, Schwarzkopf *et al.* (2011) reported that 34.9% of the patients were wearing ill-fitting shoes (of at least 0.5 size difference) and 90% did not know their shoe width. Ill-fitting shoes can lead to forefoot pathologies, such as corns, claw toes and calluses (Menz and Morris, 2005). In addition, the personalised shoe could offer exact matches for both feet as it has been suggested that the non-dominant leg is the supporting one for activities such as kicking and stepping, thus experiences more force causing the ligaments and muscles of the foot to lengthen (Cavanagh, 1980). Another finding of this research is that personalised insoles can improve foot biomechanics by spreading the peaks of plantar pressure and increasing the contact area. Although high values of plantar pressure are linked to increased discomfort and injuries (McKenzie *et al*., 1985; Jordan *et al*., 1997), this variable is more likely to benefit special populations such as rheumatoid arthritis and diabetes sufferers. It has been reported that these groups have abnormally high plantar pressures which can result in foot deformity and ulceration (Kato *et al*., 1996; Hodge *et al*., 1999).

In terms of the process, having the customer directly involved, for example seeing the foot being scanned and giving opinions (e.g. choosing comfort options) can be an advantage. The person would see firsthand the personalisation process and feel that the final product was developed using his/her input. However, it is acknowledged that some customers may just want to quickly choose their trainers without having to spend much time. The fact that marking, positioning and scanning both feet took only 10 minutes in this research indicates that the first visit does not have to be very time consuming, leaving the rest of the process to the shoe company (designing and manufacturing), which will also dictate the delivery time. Bibb *et al.* (2010) reported that using digital techniques to construct nasal prostheses can reduce the time required for the patient to be in the clinic by 2 hours and 35 minutes. The footwear personalisation process utilises electronic data, allowing companies to keep all the information, so that returning customers can purchase the product from their homes or at least shorten the period spent in store. Systems that allow the purchase of customised trainers online are already used by companies like Nike, Adidas, Reebok and New Balance, but these customised shoes are mainly concerned with aesthetics. Some also allow choice from a range of pre-existing options (width, support, midsole) and so are not strictly personalised. Digital technologies will mean a reduction in transport costs as the data can be sent electronically. Once the product is manufactured, the customer will probably have to return to the shop for the 'fitting' and make sure he/she is happy with it, similar to what was reported by Pallari *et al.* (2010) for foot orthoses. This could work like glasses prescription: the customer comes once to the shop, goes through the scanning and fitting and after that they have only to bring their 'prescription' back (which will also be stored).

7.4.2. Potential disadvantages

The first disadvantage refers to the potential high investment required in all the elements of the process for hardware, software and training. This thesis envisions that sales staff will be trained to mark and take the foot scans, a database will store customer data, a CAD specialist will design the shoe following set standards and that AM will be capable of fabricating functional midsoles. In addition, the manufactured midsole would have to be assembled in a factory using traditional techniques. In an even more complex scenario, a podiatrist could also be available in store. Protocols for the interaction between them and the CAD professional would need to be worked out. As the level of innovation proposed in this thesis is high and requires changes in all the elements of shoe manufacturing and in the current purchase experience, it is difficult for the process to be implemented for commercial purposes at this stage. The literature also reports that the current barriers for the personalisation of shoes are: higher costs, lack of sufficient production technology, lack of retailer co-operation and consumer behaviour (Redaelli *et al*., 2006).

Another disadvantage which has been exposed throughout this thesis refers to the materials available for laser sintering. In fact, not only are the number of options limited, but also the range of materials is limited and not ideal if compared to the footwear currently on the market. Also, the poor surface finish of polyamide materials makes achieving customer satisfaction from this perspective, difficult. As discussed in Section 7.2.2, the midsole material should be elastic to cushion impact with the ground and store energy, similar to EVA or polyurethane used in footwear currently. According to Hague *et al.* (2003a), materials research is one of the key areas of AM.

It is important to stress that although the results indicated lower discomfort ratings for forefoot, heel and fit with the personalised condition, there were no significant differences for ‘overall discomfort’ in the experimental trials and 4 of the matched pairs (from 13 pairs) actually rated less overall discomfort for the control condition, when compared to the personalised in the second session (month 0). As reported in Section 7.3, if the aim of personalised footwear is to reach as many people as possible, looking at the requirements of individuals is important. This is evidenced by Mundermann *et al.* (2001), who found that out of 107 individuals, 4 still preferred the control condition even though when comparing the average of comfort ratings this showed to have significantly less comfort in comparison to the 6 types of inserts analysed. A possible solution for this in the personalisation process may be the use of a cover on top of the insoles (a sock, similar to the microporous polyurethane foam used to cover the insoles in this thesis) and the customer could choose from different materials or textures to find the most comfortable. Changing only the texture of inserts (in comparison to a smooth condition) can significantly alter sensory feedback and lead to a reduction in electromyography (EMG) activity and ankle dorsiflexion at foot strike (Nurse *et al*., 2005).

Another disadvantage of the process is the potential waiting time for delivery of the shoes, which can slow sales. Customers like the instant satisfaction of having their goods at the time of purchase. However, according to Holusha (1996) customers are willing to pay a premium and wait two or three weeks for clothes that really fit, although it was not reported what percentage of total sales this would represent. Despite the fact that the estimated time for the delivery of the entire shoes has not been reported in this thesis, the 28 hours required for the manufacture of the 12 parts used in the pilot study indicates that the average delivery time of footwear customisation services like NikeID (www.nikeid.com) and mi adidas (www.miadidas.com) of 4-6 weeks can be met. In fact, the machine time depends more on filling the machine capacity (which can take 2-

3 days) rather than the manufacturing time *per se*. Also, it must be said that delays and store visit may only be required for the first purchase, while subsequent orders could be processed online, reducing costs and time. Saleh and Dalgarno (2010) estimated the time for the production of orthoses as being 7-14 days, depending on the manufacturer. However, no breakdown of this time was provided to further understand the rationale for the estimation.

7.4.3. Costs

Cost is a major factor regarding the commercial feasibility of personalised footwear. It does not matter how great the product and service are, if it is perceived to be too expensive no one will buy. It is very difficult to estimate the costs involved in personalising insoles/footwear, but existing customised products can act as a guide to some of the obvious expenses.

Starting with the materials and techniques for AM, a very good overview is given by Hopkinson (2006). He described that the price per kilogram of the materials for AM is higher than those for traditional manufacturing techniques. For example, nylon powder for laser sintering (LS) costs US$75 per kg, while Acrylonitrile-Butadiene-Styrene for injection moulding costs US$1.80. On the other hand, Hopkinson (2006) also stated that AM will be more advantageous when comparing labour costs, as manufacturing of the parts requires little technical supervision and one technician can be responsible for several machines at the same time. Finally, it has been said that the costs of AM are led by machine costs (depreciation and maintenance, accounting for around 50-75% of the costs), material costs (kilogram of material, around 20-40%) and labour costs (hourly around 5-30%), although these percentages depend on multiple factors (Hopkinson, 2006).

In terms of specific AM products, according to Gibson *et al.* (2010), a single part that fills much of the material chamber of a large LS machine can cost more than US$5,000, but for small parts such as hearing aids, costs can be only several dollars or less. Comparing AM techniques with the market, Hague *et al.* (2003b) reported that in manufacturing boxes similar to a tv cable box, using LS costs £120 and using stereolithography is £210, whereas using traditional methods it would merely cost £20.

In the orthotics sector, Saleh and Dalgarno (2010) estimated that an experienced designer can create 3 pairs of orthoses in one hour, reducing significantly the time of 1.5 hours per pair demanded in the longitudinal trial. Still according to their estimate, 5280 pairs per year can be designed at a cost of £7 per pair. They also documented that the same pair of orthotics can cost £50.66 if made using LS or £69.45 using fused deposition modelling (FDM), with the main difference being the price of the materials. Prices for custom orthoses made using conventional techniques can cost between US$100 and US$400 per pair in the United States (Davis *et al*., 2008), or an average of £82, not including the clinical costs, in the United Kingdom (Pallari *et al*., 2010). These studies, add to what was reported in Section 7.2.2, and indicate that AM is definitely ready to fabricate personalised insoles and orthotics that are commercially feasible. However, the fabrication of fully personalised footwear still requires further consideration.

For footwear customisation, the main advances to allow a better fit has been made by manufacturers of shoes for social wear (e.g. Sacco *et al*., 2003). One example is The Left Shoe Company (www.leftshoecompany.com). According to their website, the customer visits one of the shops, has both feet measured using a 3-D scanner (with the help of the staff) and the best matching last is selected based on the data. The customer can also choose the materials and colour, and the product is delivered within 4 weeks at an average starting price of 300 euros (The Left Shoe Company, 2011). Redaelli *et al.* (2006) described a laboratory to test the feasibility and practicality of the mass customisation of social shoe design and manufacturing, with an estimated premium of 20-30% on the price of the conventional shoes. There are also few cases reported in the literature about the use of AM to produce footwear. The first, and probably most famous, inspired the E2HS project (Chapter 1). A collaboration between the company Prior 2 Lever in conjunction with Loughborough University enabled the manufacture of personalised football boots using AM to reduce injury in elite players. According to Gibson *et al.* (2010), they were retailed in 2008 at a cost of £6,000 per pair. Cheaper figures were estimated by Van Der Zande *et al.* (2010) for the production of a fully AM functional lady's fashion shoe: 650 euros. These examples show that prices for AM footwear can vary significantly, depending on several factors (process, material, specialised labour, etc.), but in general it is still expensive. Hence, competing with the existing running shoe customisation systems will be extremely difficult, at least in the near future. However, similar to any technology it is expected that AM will develop over time, optimising the processes, offering a higher range of materials and making the costs more competitive.

Although the production of some products like tv boxes and footwear reported here are not commercially viable at the moment, some products such as hearing aids have been proved to be commercially successful. A good fit (which is essential for comfort and functionality) is better achieved with customisation and AM production is economically viable by allowing multiple components to be built in the same batch (therefore amortising the costs), but still keeping the customised property of each part (Eyers and Dotchev, 2010). According to Hague *et al.* (2003a), the one-off capability of AM will remove the necessity of mass production of many thousand components to pay off the costs of tooling, opening a door for AM.

7.5. Contribution to knowledge

Based on the knowledge gained in this thesis, the proposed footwear personalisation experience is summarised in Figure 7.1.

The main contribution to knowledge in this thesis is with regard to a process for the personalisation of footwear through AM. It is expected that this can serve as a reference for researchers, academics, podiatrists and personalisation professionals. In addition, this thesis contributes to existing knowledge in terms of the evaluation of personalised insoles for the short and medium term use, indicating that a geometry which matches the exact contour of someone's foot can provide benefits in terms of discomfort, plantar pressure distribution and maximum ankle eversion when compared to a generic shape. The personalisation process is flexible and can be adapted according to the tools available. For example, the research has indicated that the foot capture phase can be carried out either using a variety of static scanner or a dynamic scanner and the insole design can be conducted using a range of commercially available software.

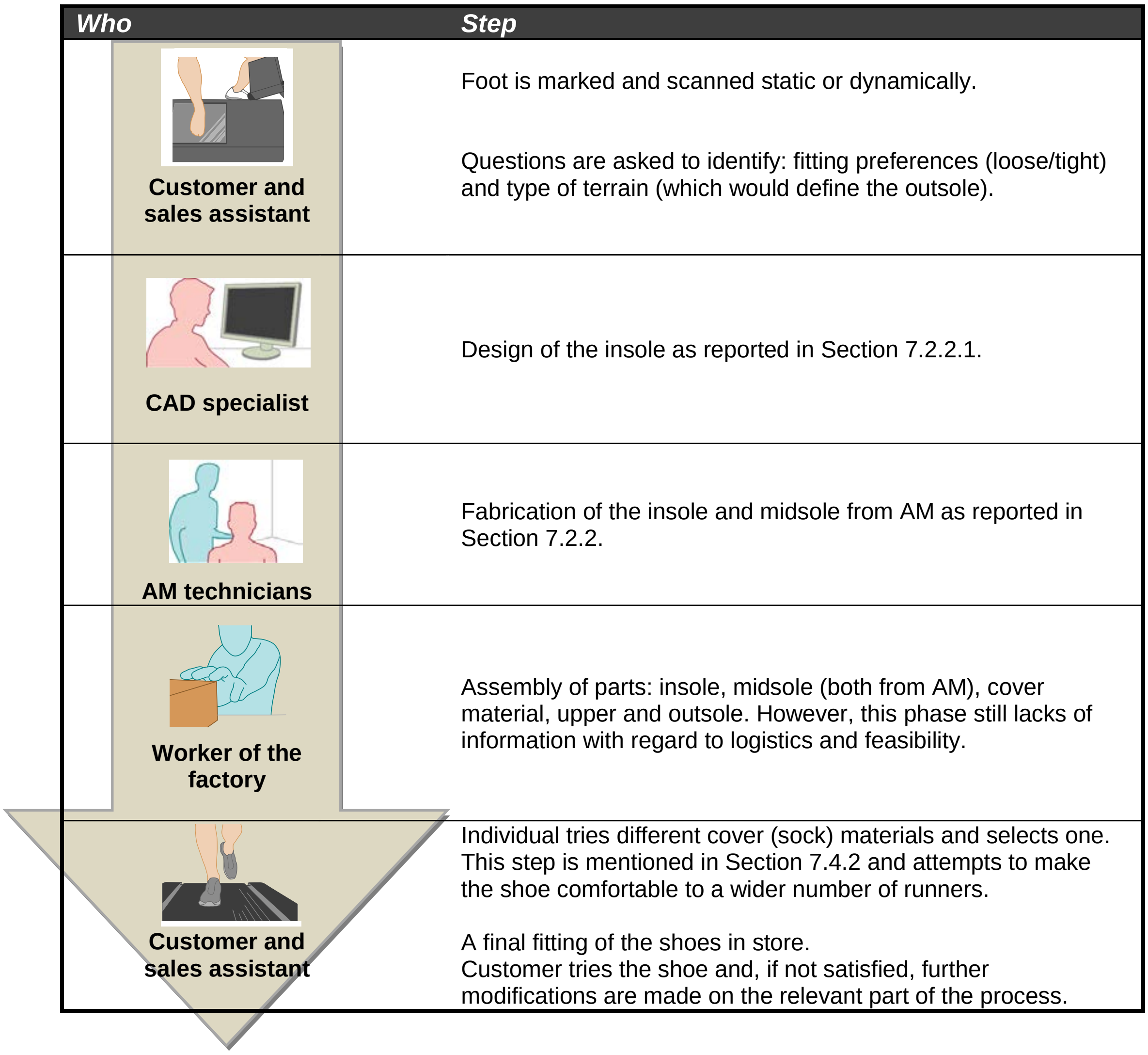


Figure 7.1. Example of a footwear personalisation purchase.

In terms of foot capture, this research has indicated that a personalised device is likely to produce better results in terms of comfort and plantar pressure distribution in comparison to a generic shape, regardless of the foot scanning position. It was shown that the scanner selection for foot capture has to consider the resolution, accuracy, scanning time and foot position as these influence the characteristics of final data and so the final design. This is the first study to explore dynamic foot scanning for the development of insoles for running footwear. Three anthropometric measurements (foot length from heel to 1st and 5th MPJs and navicular height) were necessary to specify the delimitation (length and height) of the insoles. Surprisingly, the ‘arch height’ calculations (RAD, arch index and arch ratio) did not correlate with any of the discomfort and biomechanical variables, suggesting that a linear relationship between them may not exist. The anthropometric measurements required for these calculations, therefore, may not be needed, reducing the time for this element of the process

In terms of data manipulation for the insole design, this thesis has contributed to knowledge by: (1) identifying the additional challenges when using dynamic scanning (e.g. selecting and combining different point cloud data), (2) establishing the necessary design tools (e.g. engrave and measurement of the parts) required by the software, (3) exploring the capability of both Magics and Geomagic Studio software and (4) estimating the time required to design the parts. This thesis also contributed to an exploration of the AM material (Nylon 12), which showed good durability for short and medium term use. However, the discomfort ratings taken in the laboratory sessions and Activity Diary have indicated that it may be too rigid if used in the arch region of the foot, but it was suitable for the heel cup area.

7.6. Relevance to industry

The footwear personalisation process explored in this thesis has potential in industry. As exposed in Chapter 1, technology has enabled the development of manufacturing from craft production to current mass customisation of goods. In the case of running shoes, it also has been said that some customisation is already economically feasible and exists, but a move beyond the aesthetics and fit options still has to be investigated and established. This thesis serves as a starting point for companies wanting to understand the mechanisms and implications of using AM technology. The findings can also be applied to other types of footwear and insoles as the exploration of elements of foot capture, insole design and AM have provided generic information. In addition, the overall lower discomfort ratings when wearing the personalised insoles over the short and medium term may stimulate industry to invest not only in personalised footwear, but also in better fitting shoes. Therefore, the findings are relevant for footwear designers, biomechanists, podiatrists, AM professionals and footwear companies in general, in the field of footwear and insole development.

Certain findings may be relevant for specific groups of professionals or industry sectors. The finding that none of the arch calculations correlated with the discomfort or biomechanical variables may suggest that these calculations are unable to indicate the injury risk or preferences of normal ached individuals. The scan data manipulation may be of interest to CAD professionals or footwear designers interested in modelling via reverse engineering and the research has shown the basic operations needed by the software, the challenges and the time required to manipulate the data. Finally, the findings regarding the material itself (durability, discomfort and biomechanics), and the process (time to fabricate the parts) provide useful information not only for professionals specialising in footwear, but also with AM specialists in general.

The next relevant aspect for industry is the findings with regard to the discomfort ratings in the experimental trials (supported by the Activity Diary) and the biomechanics (ankle kinematics and plantar pressure). The research has shown that the arch region of the foot requires a more flexible material or a lower arch support. This contradicts what is provided by most of the running shoes currently available on the market. The research also shows that runners have preferences whereby the heel cup is more rigid and gives the sensation of support. Finally, the research has indicated that the insole must flex to match to the individuals' MPJs otherwise it will demand that runners flex against additional resistance which may feel uncomfortable. Also, the longitudinal study has shown that runners tend to adapt better to a personalised geometry: all aspects of the foot, apart from the midfoot region, had reduced discomfort ratings over time for the 3 month period, while for the generic shape (control insoles) this reduction was only detected for the overall aspect. The personalisation of the heel cup and arch support allows plantar pressure to be redistributed, reducing higher peaks (e.g. the heel) and increasing the total contact area. This also allows a more plantar flexed position during foot strike, which can possibly reduce not only the heel pressure, but also on the vertical loading rate.

Obviously the process presented here does not refer to any fashion aspects of the shoe: colour, aesthetic design and finishing have not been considered, all of which are important for sales. Also, the process has not taken into account the current international standards for footwear development or costs. Finally, as reported previously, the state-of-art of the AM process explored in this thesis does not allow the production of functional footwear. More viable alternatives are to develop insoles for incorporation into standard off the shelf running shoes, or the production of social footwear and flip flops as these do not have as many functional requirements as running shoes (e.g. shock absorption) and have already been shown to be feasible (Van Der Zande *et al*., 2010).

7.7. Recommendations for future work

7.7.1. Further development of the personalisation process

The personalisation process developed and explored in this thesis has been shown to be ready to deliver insoles to the high street using AM, not only because it offers reduced discomfort for the short and medium term use and redistribute the plantar pressure, but also because it is economically feasible. However, unfortunately within the scope of this thesis, other materials, processes and designs could not be explored. Therefore, further research and development is necessary and the recommendations that have been made throughout this thesis will be collated and more fully explained in this section.

The findings of this thesis indicate that an insole with personalised geometry produced better outcomes in terms of discomfort and biomechanics than a generic shape for the short and medium term use. However, further research is still needed to compare methods of foot capture and establish the foot position that produces the best outcomes if a static foot capture is used. Ideally, a dynamic scanner should be used, but the methodology still needs to be defined in terms of point cloud data selection and combination, and design of the insole. The case study (Chapter 6) indicated that this is feasible using current technology, but the impact of a given design on discomfort and biomechanics still has to be established.

This thesis indicated that of the 15 anthropometric measurements taken, only 3 were used for specifying the insoles. Although the arch calculations did not correlate with the discomfort and biomechanical variables, there is still a need for further research in this area. As mentioned in Section 7.2.1.2, the literature indicates that high and low arched individuals require different support and comfort properties (e.g. Mundermann *et al*., 2001; Butler *et al*., 2006 and 2007). Therefore, in terms of personalised footwear, studies involving high/low arched runners or those with stiff/flexible arches to identify optimal properties (e.g. material hardness, insole shape) for each group needs to be investigated. One possibility is to repeat the experiment reported in Chapter 5, but with a sample consisting of equal numbers of low, normal and high arched individuals to identify differences between them. Another area for future research is to investigate how to offer pronation control tuned to the individual without the need of a specialist assessment, as described in Section 7.2.2.2.

As exposed in Section 7.3, the AM phase of the process was mainly guided by the E2HS project team. Research is required to evaluate the use of the other materials available for AM in terms of discomfort, biomechanics and durability. Some suggestions have been made in Section 7.2.2: materials that show similar mechanical properties as the ones currently used in footwear, such as EVA and polyurethane. The second large area for research is to test other AM processes for the fabrication of the parts. Since the completion of the studies reported in this thesis, AM technologies have evolved so that it is now possible to make personalised insoles using different materials. As reported in Chapter 5, this multiple material capability is enabled with 3-D printing (an AM process) allowing the production of an insole that uses a flexible material in the arch area and a rigid material for the rest. This was explored through a pilot study. A pair of personalised insoles was produced using data from a selected participant using an Objet Connex 500 machine (Objet Ltd, Rehovot, Israel). The Connex machine is capable of building parts using two different materials simultaneously. In addition, intermediate grades of material can be produced by selectively printing mixtures of these. Objet refers to them as 'digital materials' and as many as 11 different options can be produced depending on the two main materials being used. In this case, a rigid plastic material called VeroWhite was chosen for the majority of the insole part and a digital material referred to as DM_9785 was chosen for the flexible region under the arch. DM_9785 is a mixture of VeroWhite and a soft, rubber-like material called TangoPlus. The last two digits "85" indicate its Shore A hardness. The parts are shown in Figure 7.2. This pilot only explored the effectiveness of using materials with different properties to reduce the discomfort reported in the arch region in the longitudinal study. The Connex machine and material capabilities offer the potential to explore using a greater range and variety of materials across different regions on the insoles to optimise comfort and support. However, further research is necessary to evaluate this process and its materials in terms of time to fabricate the parts, range of materials, durability and potential costs involved.

Figure 7.2. Top (left) and bottom (right) views of a pair of personalised insoles developed using multiple materials.

In terms of insole design, although this thesis utilised two CAD packages (Magics and Geomagic Studio), the ideal tool for reverse engineering the insole or footwear is still unknown. As mentioned previously, there are a variety of CAD packages which need to be systematically compared in terms of accuracy, functions available and time to achieve the design. Although this thesis provided initial guidance with regard to the qualities required of the software (e.g. engraving, combining different point cloud as one single part), these need to be further established. In addition, in case of the footwear, if the design of the upper and midsole are included, additional functions/actions still have to be explored and tested.

The final, but important opportunity for research is regarding specialist design. As reported in Section 7.2.2.2, it is necessary to understand the lower limb static and dynamic evaluations required by the professional (e.g. podiatrist, physiotherapist). Prescribing orthoses is often considered a trial-and-error process and by standardising some aspects of the assessment (e.g. foot capture) there is more chance of a successful intervention. In addition, further exploration of the interactions and co-designing between specialists, such as podiatrist and the CAD designer, is needed.

7.7.2. Other research needed

In addition to the further research on the personalisation process, it remains interesting to evaluate the insoles themselves in terms of thermal sensation and performance, but using different protocol from those reported in Chapter 4. The use of any clothing implies in changes in thermoregulation (see Chapter 3), so measuring thermal sensation becomes necessary since the AM materials have not been tested with people enough for footwear applications. Also, it has been suggested that the materials of both the upper and the socks will affect the temperature and humidity of the shoe, altering thermal comfort (Cavanagh, 1980). In the pilot study, thermal sensation did not change after a 6-minute run under laboratorial conditions. Hence, research could investigate prolonged use of the footwear or insole (> 1 hour) under different temperatures. As reported in Section 7.2.2, the hygiene of LS materials (which are porous) could also be investigated as sweating and thermoregulation of the foot can promote the development of infections.

As exposed in Chapter 2, one of the aims of the running shoes is to improve performance. In the pilot study of this thesis, performance was evaluated via running economy. Although this test proved to be difficult to set up and book the laboratory for 2 consecutive days in order to get reliable data, other studies have successfully evaluated running economy wearing insoles (Hayes *et al*., 1983; Burton and Reilly, 1995). Therefore it remains necessary to investigate the impact of personalised footwear on performance, either measured by running economy or another test, such as vertical jumps.

7.8. Conclusions

The footwear personalisation process using additive manufacturing (AM) has been explored and refined throughout this thesis: 3-D scanning, anthropometric measurements and design of the parts. This research has indicated that AM shows potential in terms of delivering durable and comfortable insoles to the high street. In relation to the research questions posed in Chapter 1, the following conclusions are supported by the research in this thesis.

Q1: 'What are the measurements and foot data needed to specify personalised footwear?'

This research has indicated that 3-D scanning is suitable for capturing the foot to develop personalised footwear, but that further research is still needed into the foot scanning position (e.g. static and dynamic). From the 15 anthropometric measurements taken, only three were used in the design of the insole/footwear: foot length from the heel to the 1st and 5th MPJs and navicular height. Thus, marking the foot to take these measurements from the foot scan itself may be sufficient for the design. The arch calculations (RAD, arch index and arch ratio) did not correlate with the discomfort and biomechanical variables for the normally arched individuals recruited in this research. However, the three additional anthropometric measurements required for these calculations (foot length and dorsum height taken at 10% and 90% of weight bearing) can also be taken from the scan data if needed.

Q2: 'What design specifications are required for additive manufacturing?'

Polygon mesh manipulation type CAD software (such as Geomagic for example) has been identified as an effective tool for the design of personalised insoles for AM. The time required to design the insoles ranged from 1 to 3 hours per pair, but is highly dependent on the professional's experience. It is reasonable to assume that experience and some automation could dramatically reduce the time taken to go from scan data to insole design. In general, this thesis has indicated that the design phase can be considered the most laborious part of the personalisation process. Basic actions required for insole specification have been identified, such as: measuring of the parts to specify for their delimitations and engraving for their identification. Approximately 28 hours were taken to fabricate 12 insoles (6 pairs), from preparation of the build set-up to post-processing. The material Nylon 12 showed very good durability for the 3-month period of use, but may be too rigid for the arch region of the foot.

Q3: 'What are the benefits (if any) of a personalised pair of shoes in terms of comfort and health?'

The short and medium term use of the footwear has indicated that personalisation of the insole geometry alone can provide benefits in terms of reduced discomfort and improved biomechanics when compared to a generic shape insole (the control condition). The personalised geometry insoles had lower discomfort ratings by providing better fit and a sensation of stability in the heel cup. However, discomfort was reported in the arch area by the participants from both conditions, which is likely to be due to incorrect insole shape, coupled with the hard and inflexible material. Discomfort was also significantly reduced over the 3 month period for the personalised insoles in all regions of the foot (apart from the midfoot), but this was not the case for the control condition.

Most of the differences in the biomechanical parameters occurred during impact with the ground. Significant differences in ankle dorsiflexion at foot strike, maximum eversion and heel pressure were detected, with the personalised insoles showing lower values in comparison with the control condition. These indicate the potentially positive effect of reducing injury risk when wearing personalised insoles. The greater plantar contact area also indicates that there may be benefits in using such insoles, redistributing plantar pressure and spreading the pressure peaks.

Finally, the main limitations of the process currently are the range of materials available for laser sintering (an AM process) and the costs compared to the existing footwear. For commercial purposes, the level of innovation proposed in this thesis is high and requires changes in shoe manufacturing and also in the purchase experience. Although the costs are feasible for producing insoles, they are still high for the development of the entire footwear. However, it is expected that AM will develop over time, optimising the process, offering a greater range of materials and making the costs more competitive.

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Appendices

Appendix 1.1: Full list of Elite to High Street publications

Journal papers

HEAD, M., and PORTER, C.S. Developing a collaborative design tool for the personalisation of sports footwear. *Design Principles and Practice Journal* (in press).

HOPKINSON, N., MAJEWSKI, C.E., and ZARRINGHALAM, H., 2009. Quantifying the degree of particle melt in Selective Laser Sintering®. *CIRP Annals – Manufacturing Technology* **58**(1), 197-200.

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VINET, A., and CAINE, M. Design, manufacture and evaluation of traction features on sprint footwear using laser sintered nylon-12 sole units. *Proceedings of the Institution of Mechanical Engineers, Part P: Journal of Sports Engineering and Technology* (in press).

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Conference papers

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HEAD, M.J., PORTER, C.S., and SUMMERSKILL, S., 2009. Specifying a system to facilitate the design by consumers of personalised sports footwear. In: *Proceedings of the 5th World Congress on Mass Customization and Personalization*, Helsinki, Findland.

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Appendix 2.1: Measurements taken by Freedman *et al.* (1946) to describe three-dimensional shape of the foot

Measure	Procedure
Foot length	Length from heel to longest toe tip along rectilinear ordinates.
Ball length	Length from heel to soft tissue prominence medial to 1st MPJ.
5th to length	Length from heel to anterior 5th toe tip, along rectilinear ordinates.
Outside ball length	Length from heel to soft tissue prominence lateral to 5th MPJ, along rectilinear ordinates.
Outside ball length (diagonal)	Same as above, but measured on diagonal.
Toe length	Length from soft tissue prominence medial to 1st MPJ to longest toe tip, along rectilinear ordinates.
Breadth of 43 forward toes	The maximal breath from the medial border of the great toe to the lateral border of the 3rd toe.
Toe height	Height from the ground to the most prominent dorsal toe surface. In each case the most prominent dorsal toe surface was identified.
Height of great toe tip	Height from the ground to the dorsal surface of the tip of the great toe.
Anterior curvature and orientation of toes	Curvilinear characteristics of anterior toe margins, with orientation of their general conformation to the line connecting the 1st and 5th MPJ prominences.
Foot breadth (diagonal)	Breadth of diagonal between the prominence of the 1st and 5th MPJs.
Foot breadth (horizontal)	Breadth along a rectilinear abscissa between the longitudinal planes defined by the prominences of the 1st and 5th MPJs, and parallel to the longitudinal axis.
Foot flare	Medial or lateral deviation of the metatarsal region of the foot in relation to the heel. Expressed as a ratio of the portion of the foot breath located medial to the longitudinal plantar axis to the total foot breadth.
Ball girth	Girth just posterior to the maximal prominences of the 1st and 5th MPJs.
Ball height	Height from the ground to the dorsal foot surface in the region of the 1st MPJ.
Outside ball height	Height from the ground to the dorsal foot surface in the region of the 5th MPJ.
Angular relationship of metatarsal heads to heel	Angular relationship of the line connecting the 1st and 5th metatarso-phalangeal prominences to a line connecting the 5th metatarso-phalangeal prominence with the centre of the posterior heel rim curve.
Lateral foot contour	Contour of the lateral curved margin of the 5th and 4th toes in relation to the relatively straight lateral margin of the foot posterior to the 5th MPJ prominence.
Plantar arch height	Height from the ground to the superior margin of the plantar curvature of the arch on the medial aspect of the foot in the plant of the junction of the foot and leg.
Dorsal arch height	Height from the ground to the dorsal foot surface at the junction of the foot and leg.
Breadth of instep	Breadth of the sole in the plane of the junction of the foot and leg. In each case an estimate was made of that proportion of the total breadth which was in contact with the ground.
Instep girth	Girth in the plane of the junction of the foot and leg.
Heel breath	Breadth of the heel 45 mm forward of the posterior heel margin.
Posterior heel breadth	Contour of the posterior aspect to the heel and lower leg in the mid-sagital plane, to a height of 73 mm above the ground.
Diagonal ankle girth	Girth around posterior-inferior aspect of the heel and the dorsal
Ankle length	Length from posterior aspect of leg, 65 mm above the ground, to the junction of the foot and leg.
Lower leg girth	Girth of the leg, 125 mm above the ground.

Appendix 2.2: Measurements taken by Parham *et al.* (1992) to describe three-dimensional shape of the foot

Measure	Procedure
Calf height	The vertical distance from the standing surface to the middle of the calf landmark.
Ankle height	The vertical distance from the standing surface to the middle of the ankle landmark.
Medial malleolus height	The vertical distance from the standing surface to the middle of the medial malleolus landmark.
Lateral malleolus height	The vertical distance from the standing surface to the middle of the lateral malleolus landmark.
Dorsal arch height	Vertical distance from the standing surface to the highest point on the dorsal surface of the foot at the level of the foot-leg landmark.
Plantar arch height	The vertical distance from the standing surface to the middle of the maximum plantar arch height landmark.
Ball of foot height	The vertical distance from the standing surface to the dorsal surface of the foot at the dorsal landmark of the 1st MPJ.
1st toe height	The vertical distance from the standing surface to the highest point on the dorsal surface of the distal phalanx of the 1st toe.
Maximum toe height	The vertical distance from the standing surface to the maximum toe height landmark. Record the toe measured. The hallux is excluded from consideration for this measurement.
Outside ball of foot height	The vertical distance from the standing surface to the dorsal surface of the foot at the dorsal landmark of the 5th MPJ.
Calf circumference	Measured as the circumference of the calf at the level of the calf landmark
Ankle circumference	Measured as the minimum circumference of the leg at the level of the ankle landmark.
Heel-ankle circumference	The diagonal circumference of the foot with the tape passing over the foot-leg landmark and around the base of the heel.
Instep circumference	The circumference of the instep over the medial, dorsal, and lateral instep circumference landmarks.
Ball of foot circumference	Measured as the maximum circumference of the right foot over the 1st and 5th MPJs landmarks, in a plane oblique to the long axis of the foot.
Heel breadth	Measured as the maximum horizontal breadth of the right heel.
Ball of foot breadth, diagonal	Measured as the breadth of the foot at the medial landmarks of the 1st and 5th MPJs.
Ankle length	The length from the heel to the anterior limit of the ankle.
Instep length	Having a plain block aligned at the instep circumference landmark, the instep length was measured on the scale of the box the length from the heel to the anterior limit of the instep.
Ball of foot length	The length from the heel to the ball of the foot.
Foot length	Anterior tip of the most protruding toe, measure on the scale of the box the length of the right foot.
Ball of foot breadth, horizontal	With a plain block touching the widest part of the right foot at the 1st MPJ, measure on the scale of the box, the breadth of the foot.
Outside ball of foot length	With a plain block touching the foot at the medial landmark of the 5th MPJ, measure on the scale of the box the length from the heel to the outside ball of the foot.
5th toe length	With a plain block touching the foot at the anterior tip of the 5th toe, measure on the scale of the box the length from the heel to the tip of the 5th toe.
Bi-malleolar breadth	Using a calliper, brush the medial and lateral malleoli, when the arms of the calliper are moved up and down, parallel to the long axis of the foot
1st-3rd toe breadth	Measured as the maximum breadth from the medial border of the 1st (great) toe to the lateral border of the 3rd toe

Appendix 4.1: Participant information sheet (pilot study)

Participant Information Sheet

Investigator: André Salles mobile: 07533 765 042 e-mail: a.s.salles@lboro.ac.uk
Supervisors: Dr. Diane Gyi and Prof. Mark Porter

What is the purpose of the study?
The purpose of this study is to develop personalised footwear for runners and evaluate them in terms of comfort, performance and biomechanics.

Who is doing this research?
The team involved in this research are Dr. Diane Gyi from Human Sciences Department, André Salles and Prof. Mark Porter from the Department of Design and Technology. This research is part of the 'Elite to High Street' project at Loughborough University.

What do I have to do in order to be included?
You need to regularly run at least 5 km per week and be between 18 to 65 years old.

Once I take part, can I change my mind?
Yes! Once you agree to take part you will be asked to sign a consent from. However, you can change your mind and withdraw at any time without giving a reason.

How many sessions I will be required to attend? For how long?
You will be asked to come into four sessions. Sessions 1 and 2 may take 40 minutes each; sessions 3 and 4 may take 1 hour and 15 minutes each.

What do I have to do?
Meet with the investigator at the arranged times and venue. In session 1 you will be asked to fill in a questionnaire and be measured. In sessions 2, 3 and 4 you will be asked to run on a treadmill. In sessions 3 and 4 you will be asked to run for 10 meters whilst some biomechanical data are collected and give your opinion in terms of comfort. A sheet with some guidelines for the physiological tests will be given to you prior session 2.

Where will the sessions take place?
All sessions will be held at:
Loughborough University Sports Technology Institute
Loughborough Science & Enterprise Park
1 Oakwood Drive, Loughborough, LE11 3QF
A map can be found at: http://www.lboro.ac.uk/about/map/pages/map-holywellpark-lrg.html

What personal information will be required from me?
Both your feet will be measured and scanned in order to produce the personalised footwear. In addition, your age, height, mass as well as your maximal oxygen consumption will be required.

What happens if something goes wrong?
We will follow the incident reporting procedure at Loughborough University and your organization currently. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due someone's negligence, then you

may have grounds for a legal action but you may have to pay for it. Agreeing to take part does not affect your legal rights (e.g. to compensation, in the unlikely event of event of injury).

Will my taking part in this study be kept confidential?
The information will be kept in a secure location, accessible only to the researchers. All references to the participants in the report and any subsequent publications/presentations will be anonymous.

What will happen to the results of the study?
The results will be coded (for anonymity) and analysed by the research team before being reported. Results may be published in scientific journal and conferences. If you take part in this research, you can obtain copies of these publications from the research team. The data will be stored by André Salles at Loughborough University under the conditions specified by the Departmental Data Protection Advisor. Your name will not be disclosed to anyone at any time.

What do I get from participating?
You will be contributing to science and the development of personalised footwear. Also, the pair of New Balance trainers used in the experiment will be given to you at the end of session 4.

What if I have any concerns?
You can contact André Salles, the investigator, at any time on his mobile: 07533 765 042 or e-mail address: a.s.salles@lboro.ac.uk

Many thanks for your attention!

Appendix 4.2: Physical activity and heath screen questionnaire (pilot study)

Physical Activity and Health Screen Questionnaire

Phd Student: André Salles
Supervisor: Dr. Diane Gyi

Participant Number: ☐☐ **Male** ☐ **Female** ☐

1. Background details

(i) Age: _________

(ii) How many Kilometres do you approximately run per week? ________km

(iii) How many Kilometres do you approximately run per week? Yes ☐ No ☐

____

____

(iv) Have you suffered from any musculoskeletal injuries in the last twelve months? If yes, please provide details Yes ☐ No ☐

____

____

2. Health Questionnaire

As a volunteer participating in a research study, it is important that you are currently in good health and have had no significant medical problems in the past. This is (i) to ensure your own continuing well-being and (ii) to avoid the possibility of individual health issues confounding study outcomes.

- If you have a blood-borne virus, or think that you may have one, please do not take part in this research.

Please complete this brief questionnaire to confirm your fitness to participate:

a. **At present,** do you have any health problem for which you are:

(i)	on medication, prescribed or otherwise	Yes	☐	No	☐
(ii)	attending your general practitioner	Yes	☐	No	☐
(iii)	on a hospital waiting list	Yes	☐	No	☐

b. **In the past two years,** have you had any illness which required you to:

(i)	consult your GP..	Yes	☐	No	☐
(ii)	attend a hospital outpatient department	Yes	☐	No	☐
(iii)	be admitted to hospital	Yes	☐	No	☐

c. **Have you ever** had any of the following:

(i)	Convulsions/epilepsy	Yes	☐	No	☐
(ii)	Asthma	Yes	☐	No	☐
(iii)	Eczema	Yes	☐	No	☐
(iv)	Diabetes	Yes	☐	No	☐
(v)	A blood disorder	Yes	☐	No	☐
(vi)	Head injury	Yes	☐	No	☐
(vii)	Digestive problems	Yes	☐	No	☐
(viii)	Heart problems	Yes	☐	No	☐
(ix)	Problems with bones or joints	Yes	☐	No	☐
(x)	Disturbance of balance/coordination	Yes	☐	No	☐
(xi)	Numbness in hands or feet	Yes	☐	No	☐
(xii)	Disturbance of vision	Yes	☐	No	☐
(xiii)	Ear / hearing problems	Yes	☐	No	☐
(xiv)	Thyroid problems	Yes	☐	No	☐
(xv)	Kidney or liver problems	Yes	☐	No	☐
(xvi)	Allergy to nuts	Yes	☐	No	☐

d. **Has any,** otherwise healthy, member of your family under the age of 35 died suddenly during or soon after exercise? .... Yes ☐ No ☐

If YES to any question, please describe briefly if you wish (eg to confirm problem was/is short-lived, insignificant or well controlled.)

....
....
....
....
....

e **Additional questions for female participants**

(a)	are your periods normal/regular?	Yes ☐	No ☐
(b)	are you on "the pill"?	Yes ☐	No ☐
(c)	could you be pregnant?	Yes ☐	No ☐
(d)	are you taking hormone replacement therapy (HRT)?	Yes ☐	No ☐

Appendix 4.3: Consent form (pilot study)

Loughborough University

Consent Form

Ethics Committee Approval Number: R08-P86

Participant Number | | |

I consent to taking part in these tasks to collect data to help researchers develop personalised footwear.

An explanation of the nature and purpose of the research has been given to me by the researcher.

I understand that I may withdraw from the study at any time, and that I am not under obligation to give reasons.

I understand that foot and leg measurements will be taken.

I understand that my foot will be scanned and that personalised footwear will be developed.

I understand that measures of foot pressure distribution, oxygen used and joint angles will be taken. These will be explained during the sessions.

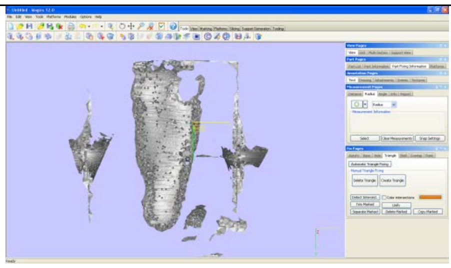
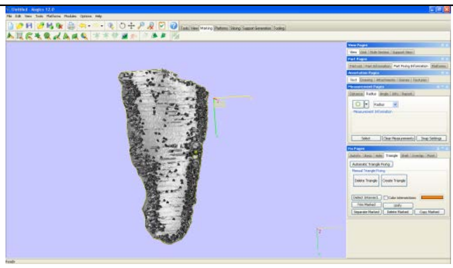
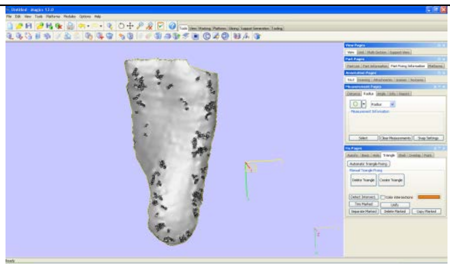
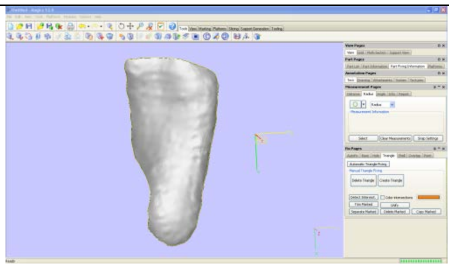
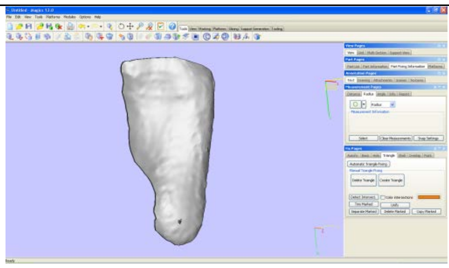
I understand that these and all information about myself will be anonymised and treated as strictly confidential by the research team.

Signed:

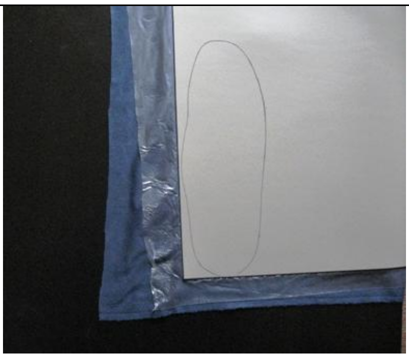
Date: ____/____/____

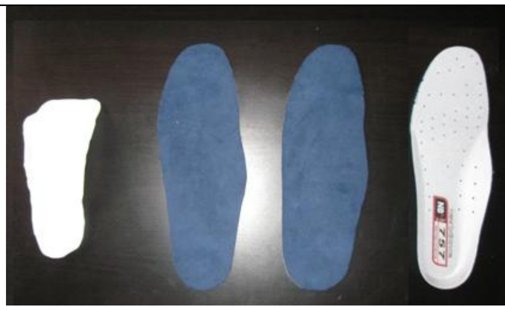
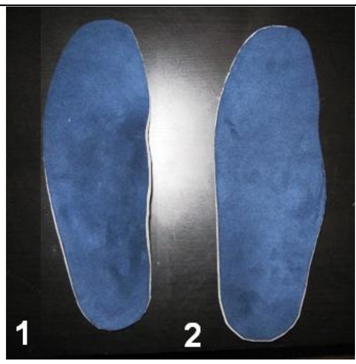
Signature of researcher:

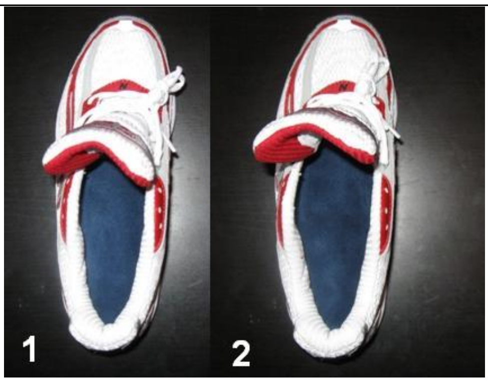
Appendix 4.4: Process of designing the personalised insoles used in the pilot

Phase	Action	Illustration (Magics)
1 – raw data	Open the file in Magics software (version: 12.0.0.19; Materialise Leuven, Belgium).	
2 – unwanted data deletion	Unwanted data is deleted.	
3 – data smoothing	The entire part is smothered to reduce ‘noise’ in the data.	
4 – data and boundary smoothing	Jagged edges on the boundary is smothered by creating new triangles and the entire data is smothered further.	
5 – Extruding	Extruding in 3 mm in the Z direction	

Appendix 4.5: Process of constructing the two conditions (control and personalised) for the pilot study

Phase	Description	Illustration
1 – getting the standard insole and the microporous polyurethane foam	Standard insole is served as a reference for cutting the foam on the appropriate shape for both conditions.	
2 – drawing the insole	A line is drawn.	
3 – finish the drawing	The foam is now ready to be cut.	
4 – foam is cut	Foam being cut following the line.	

5 – insole sanding	Personalised insole was sanded down to eliminate sharp edges and make smoother.	
6 – insoles before gluing	The personalised insole, the foam that will be glued over it, followed by the foam and the standard insole.	
7 – insoles after gluing	Both conditions with their respective foams covering; 1 = personalised, 2 = control.	
8 – personalised condition	Bottom view of the personalised condition.	
9 – trainers	New Balance shoes used in the experiment.	

10 – conditions finished	Finally, the two conditions ready for the trial; 1 = control and 2 = personalised.	

Appendix 4.6: Guidelines for participants for the physiological testing (pilot study)

Guidelines for participants for the physiological testing

Investigator: André Salles mobile: 07533 765 042 e-mail: a.s.salles@lboro.ac.uk
Supervisor: Dr. Diane Gyi

These guidelines should be followed on the days preceding both physiological tests sessions (running economy). Please wear light and comfortable sportswear, the same ones for all trials.

<u>Guidelines for 48 hours before test:</u>

- Refrain from heavy exercise. Light exercise can be undertaken;
- A meal high in carbohydrates should be consumed (e.g. pasta, bread, potato).

<u>Guidelines for 24 hours before test:</u>

- No exercise should be undertaken.
- A meal high in carbohydrates should be consumed (e.g. pasta, bread, potato).
- No alcohol should be taken.

<u>Day of testing:</u>

- Avoid smoking.
- No exercise should be undertaken.
- A meal (e.g. sandwich, yogurt) 2 to 4 hours before testing should be consumed but nothing thereafter. If the test is conducted in the morning, a light breakfast (e.g. 2 slices of toast plus fruit juice) should be consumed.
- Adequate fluids should be taken but no caffeine (tea and coffee) or sports drink should be consumed in the four hours prior the test. You should be hydrated.

Please wear light and comfortable clothing (e.g. shorts, trainers and t-shirt). The <u>same clothes</u> should be worn for both tests.

Venue: Loughborough University Sports Technology Institute
Loughborough Science & Enterprise Park
1 Oakwood Drive, Loughborough, LE11 3QF
A map can be found at: http://www.lboro.ac.uk/about/map/pages/map-holywellpark-lrg.html

Running economy I:	Running economy II:
Date: ____/____/____	Date: ____/____/____
Time: ____h____min	Time: ____h____min

Appendix 4.7: Visual analog scale (pilot study)

Loughborough University

Pilot Study

Self-perceived discomfort data sheet

Subject Number: ________ Date: _____/_____/_____

Condition: ________

	most comfortable condition imaginable	not comfortable at all
overall comfort	|————	————|
forefoot	|————	————|
midfoot	|————	————|
heel	|————	————|
arch	|————	————|
fit	|————	————|

There are several aspects of the shoes which we are interested in measuring:

overall comfort	overall comfort of the shoe
forefoot	comfort of the insole at the forefoot area
midfoot	comfort of the insole at the midfoot area
heel	comfort of the insole at heel area
arch	arch comfort
fit	fit of the insole to the foot, whether the insole is loose or tight

There are scales for measuring each of these aspects of shoes. Although some insole aspects may be equally comfortable we would like you to judge the aspects independently. Please mark the line to indicate the relative discomfort of a specific insole condition; the further to the right, the more uncomfortable the insole. Similarly, mark the other lines to indicate the discomfort of the specific shoe aspects.

Appendix 4.8: Thermal sensation scale (pilot study)

Loughborough University

Pilot Study

Self-Perceived Thermal Comfort

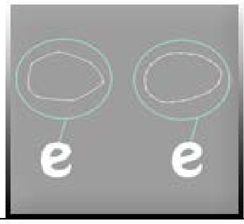
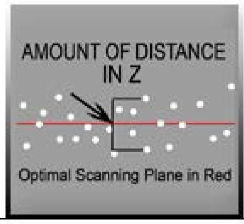
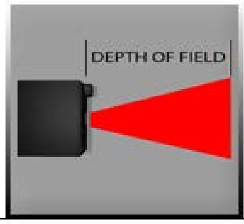
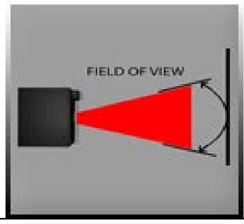
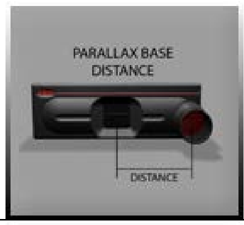
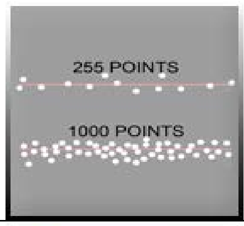
Subject Number: ________ Date: _____/_____/_____

Condition: ________

How is the overall thermal state of your feet:

+3	hot
+2	warm
+1	slightly warm
0	neutral
-1	slightly cool
-2	cool
-3	cold

Appendix 5.1: Specifications of each camera of the foot scanner used in the longitudinal study (source: escan3d.com/?page_id=11)

Specification	Value	Illustration
Resolution	Between 0.135 mm and 0.210 mm at a depth of 300 mm and 650 mm, respectively.	
Deviation from ideal scanning plane	Between 0.150 mm and 0.250 mm at a depth of 300 mm and 650 mm, respectively.	
Depth of field	Between 300mm and 650mm	
Field of view	40 Degrees	
Parallax base distance	4.33″ (110mm) 9″ (228mm) 17″ (432mm)	
Point density	255 points per line	
Dimensions of scanner	210 × 245 x 120 mm	

Appendix 5.2: Poster used to recruit participants for the longitudinal study

JOGGERS AND RUNNERS NEEDED

- Do you jog or run at least 5 km a week?
- Are you 18 – 65 years old?
- Do you want to contribute to research into the design of trainers?

If the answers to these questions are **‘yes’**, then we need your help.

We are keen to recruit recreational runners for cutting-edge research on running shoe design. Even if you only walk and jog! We will provide a pair of running shoes for your physical activity and will ask you to attend 4 laboratory sessions during a 3 month period.

If you are interested, please contact me for more details.

Mr. André Salles 01509 228313
a.s.salles@lboro.ac.uk
Department of Design and Technology

Loughborough University

Appendix 5.3: Participant information sheet (longitudinal study)

Loughborough University

Participant Information Sheet

Investigator: André Salles mobile: 07533 765042 e-mail: a.s.salles@lboro.ac.uk

Supervisor: Dr. Diane Gyi telephone: 01509 223043 e-mail: d.e.gyi@lboro.ac.uk

What is the purpose of the study?
The project aims to evaluate the short and medium term use of different footwear trainers in terms of discomfort and biomechanics.

Who is doing this research?
The team involved in this research are Dr. Diane Gyi from Human Sciences Department and André Salles from the Department of Design and Technology. This research is part of the 'Personalised Sports Footwear: from Elite to High Street' project at Loughborough University.

What do I have to do in order to be included?
You need to regularly run at least 5 km per week and be between 18 to 65 years old.

Once I take part, can I change my mind?
Yes! Once you agree to take part you will be asked to sign a consent from. However, you can change your mind and withdraw at any time without giving a reason. Please just let us know.

How many sessions I will be required to attend? For how long?
You will be asked to come to four sessions. Session 1 should take 40 minutes; sessions 2, 3 and 4 should take 1 hour and 15 minutes each.

What do I have to do?
Meet with the investigator at the arranged times and venue. In session 1 you will be asked to fill in a questionnaire, be measured and both your feet will be scanned. In sessions 2, 3 and 4 you will be asked to run for 10 meters whilst some biomechanical data are collected and give your opinion in terms of comfort. Between each session you will be asked to wear the footwear provided every time you go jogging or running for 3 months and complete an Activity Diary explaining how many steps did you take (pedometers will be given to you) and any discomfort felt.

What happens if I experience any discomfort or pain using the footwear?
It is important for us to know if you experience any undue discomfort and pain from using the footwear. If you do so, please stop wearing them immediately and contact André Salles (07533 765042 or email: a.s.salles@lboro.ac.uk) as soon as possible.

Where will the sessions take place?
All sessions will be held at:
Loughborough University Sports Technology Institute
Loughborough Science & Enterprise Park
1 Oakwood Drive, Loughborough, LE11 3QF
A map can be found at: http://www.lboro.ac.uk/about/map/pages/map-holywellpark-lrg.html

What personal information will be required from me?
Both your feet will be measured and scanned in order to produce the footwear. In addition, your age, height, mass as well as some body size measures will be taken.

What happens if something goes wrong?
We will follow the incident reporting procedure at Loughborough University and your organisation currently. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Agreeing to take part does not affect your legal rights (e.g. to compensation, in the unlikely event of event of injury).

Will my taking part in this study be kept confidential?
The information will be kept in a secure location, accessible only to the researchers. All references to the participants in the report and any subsequent publications/presentations will be anonymous.

What will happen to the results of the study?
The results will be coded (for anonymity) and analysed by the research team before being reported. Results may be published in scientific journal and conferences. If you take part in this research, you can obtain copies of these publications from the research team. The data will be stored by André Salles at Loughborough University under the conditions specified by the Departmental Data Protection Advisor. Your name will not be disclosed to anyone at any time.

What do I get for participating?
You will be contributing to the science and the development of personalised footwear. Also, you will be allowed to keep the pair of New Balance trainers used in the study[1].

What if I have any concerns?
You can contact André Salles, the investigator, at any time on his mobile: 07533 765 042 or e-mail address: a.s.salles@lboro.ac.uk

Many thanks for participating!

[1] **NB**. The University's insurance cover and liability for injuries sustained does *not* cover wearing the New Balance shoes *after* completion of the study.

Appendix 5.4: Physical activity and heath screen questionnaire (longitudinal study)

Loughborough University

Physical Activity and Health Screen Questionnaire

PhD Student: André Salles
Supervisor: Dr. Diane Gyi

Participant Number: ☐☐ **Male** ☐ **Female** ☐

1. Background details

(i) Age: _________

(ii) How many Kilometres do you approximately run per week? ________km

(iii) How many Kilometres do you approximately run per week? Yes ☐ No ☐

____

____

(iv) Have you suffered from any musculoskeletal injuries in the last twelve months? If yes, please provide details Yes ☐ No ☐

____

____

(v) What is your trainers size (British standard)? ________

(vi) For how many months/years have you been running ________years
________months

2. Health Questionnaire

- As a volunteer participating in a research study, it is important that you are currently in good health and have had no significant medical problems in the past. This is (i) to ensure your own continuing well-being and (ii) to avoid the possibility of individual health issues confounding study outcomes.

Please complete this brief questionnaire to confirm your fitness to participate:

a. **At present,** do you have any health problem for which you are:

(i)	on medication, prescribed or otherwise	Yes	☐	No	☐
(ii)	attending your general practitioner	Yes	☐	No	☐
(iii)	on a hospital waiting list	Yes	☐	No	☐

b. **In the past two years,** have you had any illness which required you to:

(i)	consult your GP...	Yes	☐	No	☐
(ii)	attend a hospital outpatient department	Yes	☐	No	☐
(iii)	be admitted to hospital	Yes	☐	No	☐

c. **Have you ever** had any of the following:

(i)	Convulsions/epilepsy	Yes	☐	No	☐
(ii)	Asthma	Yes	☐	No	☐
(iii)	Eczema	Yes	☐	No	☐
(iv)	Diabetes	Yes	☐	No	☐
(v)	A blood disorder	Yes	☐	No	☐
(vi)	Head injury	Yes	☐	No	☐
(vii)	Digestive problems	Yes	☐	No	☐
(viii)	Heart problems	Yes	☐	No	☐
(ix)	Problems with bones or joints	Yes	☐	No	☐
(x)	Disturbance of balance/coordination	Yes	☐	No	☐
(xi)	Numbness in hands or feet	Yes	☐	No	☐
(xii)	Disturbance of vision	Yes	☐	No	☐
(xiii)	Ear / hearing problems	Yes	☐	No	☐
(xiv)	Thyroid problems	Yes	☐	No	☐
(xv)	Kidney or liver problems	Yes	☐	No	☐
(xvi)	Allergy to nuts	Yes	☐	No	☐

d. **Has any,** otherwise healthy, member of your family under the age of 35 died suddenly during or soon after exercise? .... Yes ☐ No ☐

If YES to any question, please describe briefly if you wish (eg to confirm problem was/is short-lived, insignificant or well controlled.)

....
....
....
....
....

e **Additional questions for female participants**

(a)	are your periods normal/regular?	Yes	☐	No	☐
(b)	are you on "the pill"?	Yes	☐	No	☐
(c)	could you be pregnant?	Yes	☐	No	☐
(d)	are you taking hormone replacement therapy (HRT)?	Yes	☐	No	☐

Appendix 5.5: Consent form (longitudinal study)

Loughborough University

Consent Form

Ethics Committee Approval Number: R09-P64

Participant Number | | |

I consent to taking part in these tasks to collect data to help researchers develop personalised footwear.

An explanation of the nature and purpose of the research has been given to me by the researcher.

I understand that I may withdraw from the study at any time, and that I am not under obligation to give reasons.

I understand that body size measurements will be taken.

I understand that my feet will be scanned and that footwear will be provided for my use during jogging/running.

I understand that measures of foot pressure distribution and joint angles will be taken. These will be explained during the sessions.

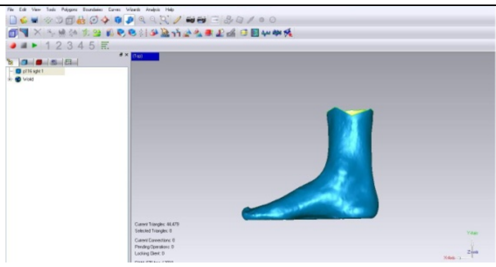
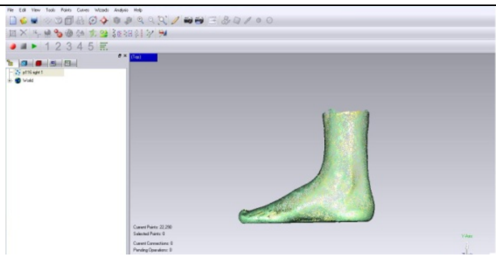
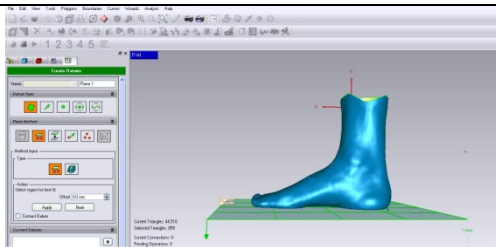
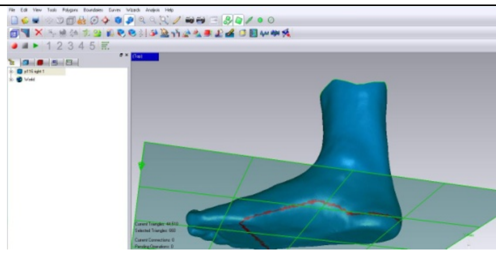
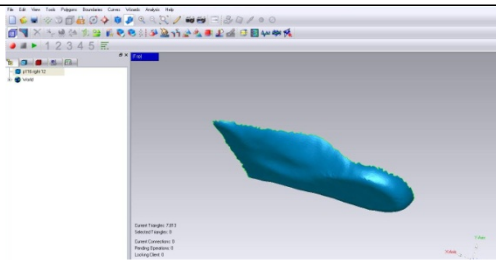
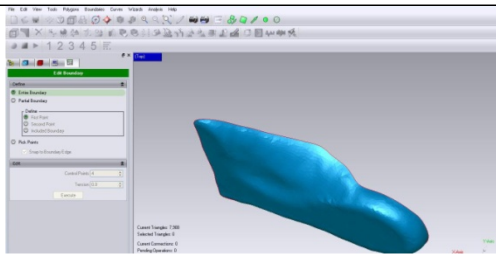
I understand that these and all information about myself will be anonymised and treated as strictly confidential by the research team.

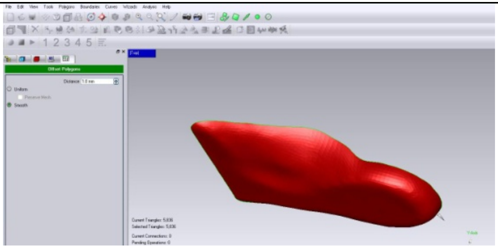
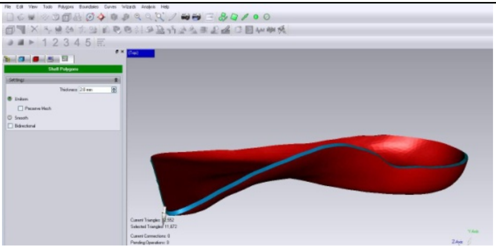
Signed:

Date: ____/____/____

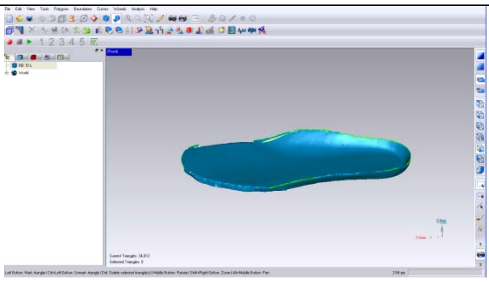
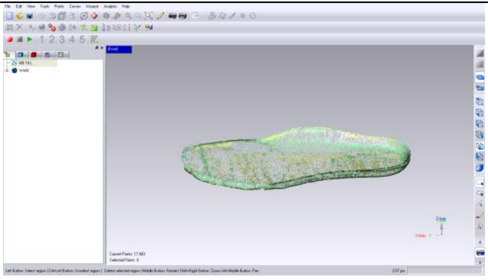
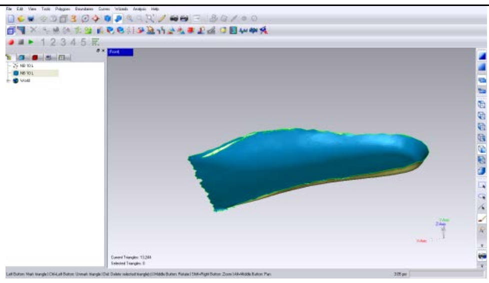
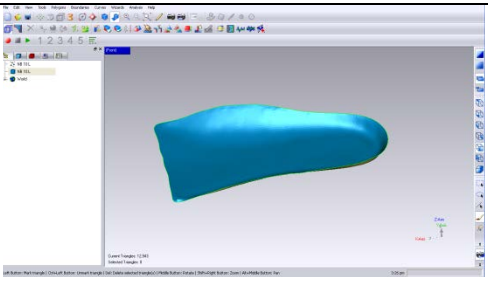
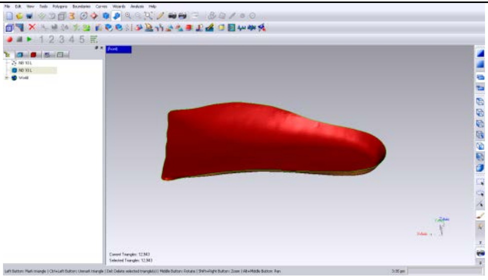
Signature of researcher:

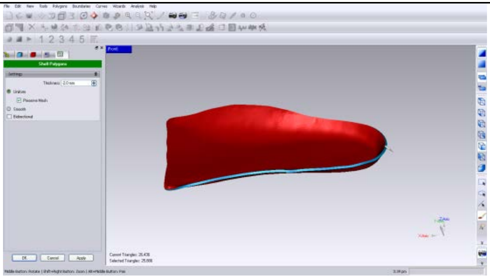
Appendix 5.6: Process of designing the personalised insoles used in the longitudinal study

Phase	Action	Illustration (Geomagic Studio)
1 – raw data	Open the file in Geomagic Studio 10 software (version: 10; Geomagic Inc, Durham, USA).	
2 – noise reduction	Compensation for scanner error (noise) by moving points to statistically correct locations.	
3 – plane datum creation	Construction of an imaginary plane to help identify points.	
4 – selection of points	15 mm is measured from the datum to the foot and 3 points on the heel are marked. The navicular, 1st and 5th MPJs are identified and marked. Then, a line is drawn passing through the marks.	
5 – unwanted data deletion	Unwanted data is deleted.	
6 – boundary smoothing	Jagged edges on the boundary is smoothed by reconstructing the polygon mesh.	

Phase	Action	Illustration (Geomagic Studio)
7 – offset by 1 mm	Expansion of the data by 1 mm in the outward direction.	
8 – thicken by 2 mm	Increase the part width of the data surface by 2 mm in the outward direction.	

Appendix 5.7: Process of designing the control insoles used in the longitudinal study

Phase	Action	Illustration (Geomagic Studio)
1 – raw data	Open the file in Geomagic Studio 10 software (version: 10; Geomagic Inc, Durham, USA).	
2 – noise reduction	Compensation for scanner error (noise) by moving points to statistically correct locations.	
3 – unwanted data deletion	Because the original insole scanned is 5 mm thick, the data from the bottom part is selected, together with the forepart and deleted.	
4 – boundary smoothing	Jagged edges on the boundary is smoothed by reconstructing the polygon mesh.	
5 – shell by 2 mm	Modification of the data to be 2 mm smaller, creating an additional polygon surface.	

Phase	Action	Illustration (Geomagic Studio)
6 – thicken by 2 mm	Increase the part width of the data surface by 2 mm in the outward direction.	

Appendix 5.8: How the PiG calculates the joint centres and angles (from Vicon, 2010)

To calculate the joint angles, moment and power with inverse dynamics, the Vicon's PiG calculates first the centre of the joints. It determines the hip joint centre from the four markers placed on the pelvis. The knee joint centre is then calculated using the markers on the thigh and knee, together with the hip joint centre (Figure 1).

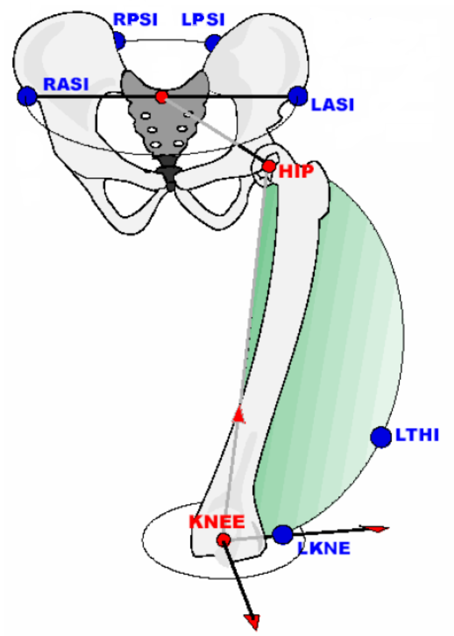


Figure 1. PiG determination of the knee joint centre.

Finally, the ankle joint centre is calculated using the shin, lateral malleolus, heel and forefoot markers, together with the knee joint centre (Figure 2).

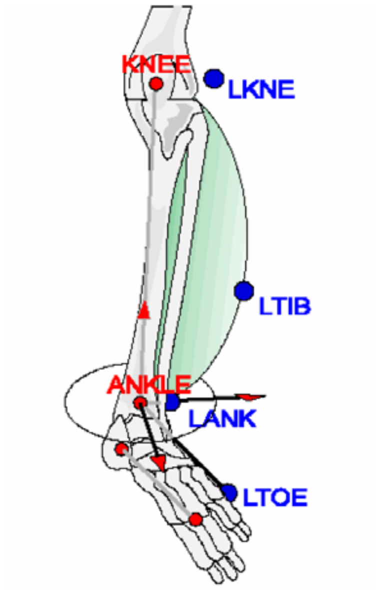


Figure 2. PiG determination of the ankle joint centre.

According to Vicon (2010), the joint angles in the PiG are estimated using the following ordered rotations (Figure 3): (1) the first rotation (flexion) is made about the common flexion axis; (2) second rotation (abduction) is made about the abduction axis of the moving element; (3) third rotation (rotation) is made about the rotation axis of the moving element.

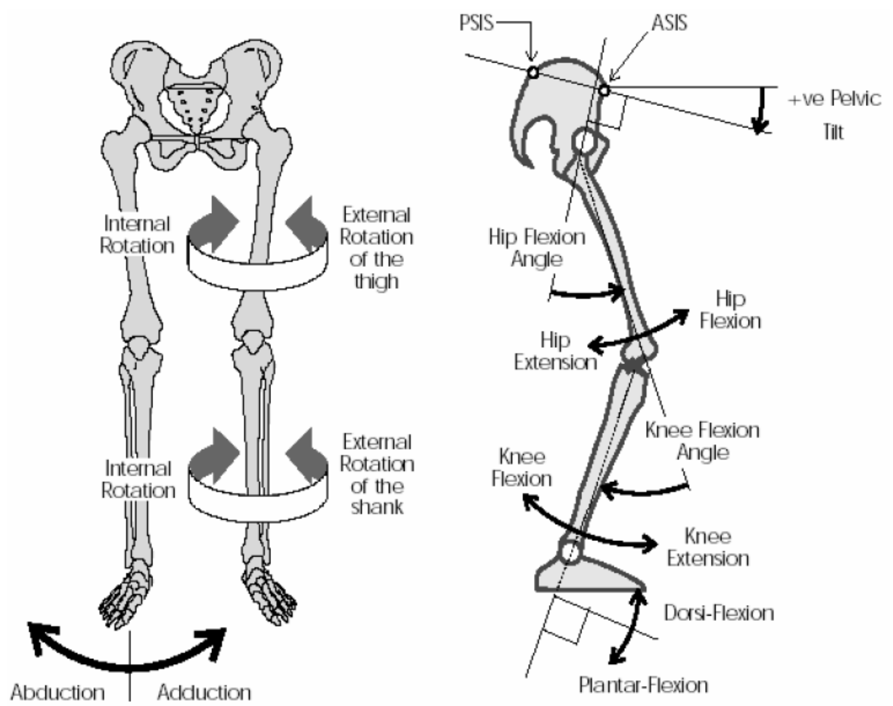


Figure 3. PiG kinematic variable definitions.

Joint angles are also described by Vicon (2010) using goniometric information. Using goniometric definitions, a joint angle is described by the following: (1) flexion is about the flexion axis of the proximal (or absolute) element; (2) rotation is about the rotation axis of the distal element; (3) abduction axis 'floats' so as always to be at right angles to the other two.

Appendix 5.9: Visual analog scale (longitudinal study)

Loughborough University

Longitudinal Study

Self-perceived discomfort data sheet

Participant Number: ________ Date: _____/_____/_____

	most comfortable condition imaginable imaginable	not comfortable at all
overall comfort	|————————————	————————————|
forefoot	|————————————	————————————|
midfoot	|————————————	————————————|
heel	|————————————	————————————|
arch	|————————————	————————————|
fit	|————————————	————————————|

There are several aspects of the shoes which we are interested in measuring:

overall comfort	overall comfort of the shoe
forefoot	comfort of the insole at the forefoot area
midfoot	comfort of the insole at the midfoot area
heel	comfort of the insole at heel area
arch	arch comfort
fit	fit of the insole to the foot, whether the insole is loose or tight

There are scales for measuring each of these aspects of shoes. Although some insole aspects may be equally comfortable we would like you to judge the aspects independently. Please mark the line to indicate the relative discomfort of a specific insole condition; the further to the right, the more uncomfortable the insole. Similarly, mark the other lines to indicate the discomfort of the specific shoe aspects.

Appendix 5.10: Activity Diary (longitudinal study)

Loughborough University's research on footwear evaluation

Activity Diary

2009

Researcher: André Salles
E-mail: a.s.salles@lboro.ac.uk
Mobile: 07533 765042
Office: 01509 228313

Many thanks for taking part in this research! Your help is very important. Please read carefully the instructions below.

Please wear the New Balance shoes for your jogging/running sessions only. Do not use them for any other type of activity (e.g. go shopping, playing tennis, etc.). Remember to complete this diary immediately after each jogging/running session.

If you have any concerns or problems, please contact André Salles to discuss. If you experience a lot of discomfort or pain from wearing the running shoes, please stop wearing them immediately and contact André to inform that.

The following pages detail how to complete this diary as well as how to use your pedometer. In the 3rd laboratory session, André will collect the completed sheets and provide you with some more. In the 4th session, André will collect all remaining sheets.

We hope you have an enjoyable 3 months of training!

How to complete the activity diary:

Date ____/____/____

(ie. dd/mm/yy)

Time of start: _____ **am** ☐ **pm** ☐

The time you've started your running session (eg. 6 pm).

(i) For how long did you run? ________minutes

How many minutes was your entire running/jogging session (eg. 75 minutes)

(ii) How many steps did you take? ________steps

Please refer to your pedometer. Remember to always reset your pedometer before the running session

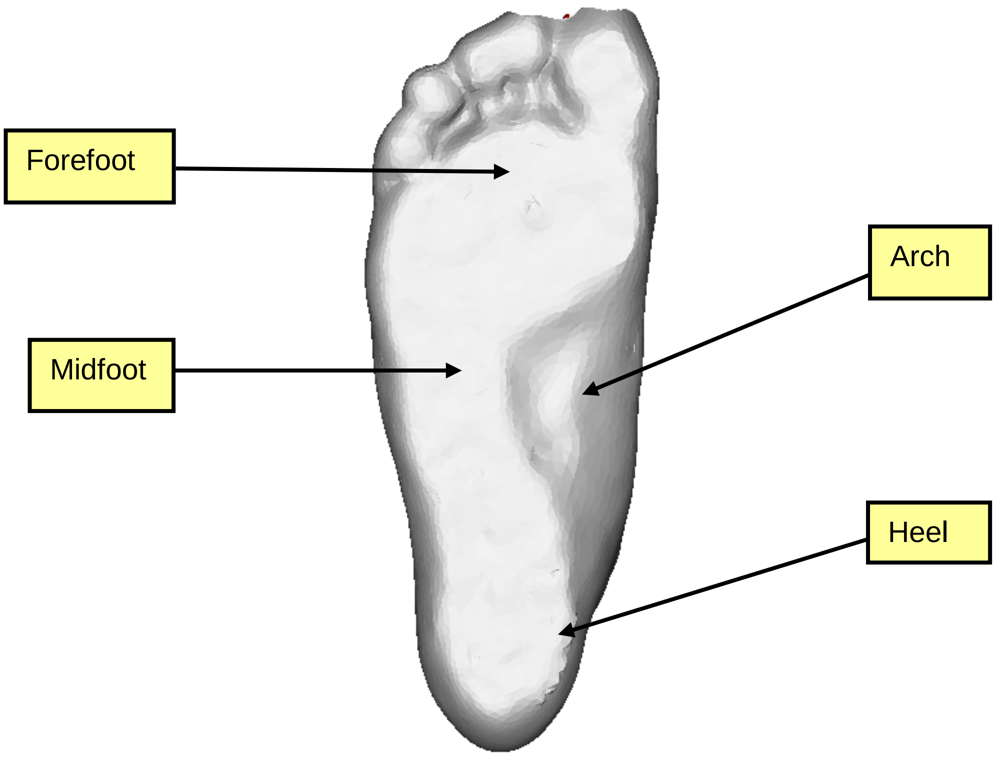
(iii) Did you feel any discomfort during the training session? If yes, please complete sections iv and v. Yes ☐ No ☐

Any type of discomfort you may experience. For instance, if an uneven surface could have led you to a discomfort in the knee.

Please turn over

In question iv, 6 areas of the foot are presented and an option for ‘other’. Please mark the line to indicate any relative discomfort; the further to the left, the more comfortable the shoe. Please see below an explanation of each aspect:

- overall comfort – overall discomfort of the shoe
- forefoot – discomfort in the forefoot area
- midfoot – discomfort in the midfoot area
- heel – discomfort in the heel area
- arch – arch discomfort
- fit – fit of the shoe to the foot, whether it is loose or tight
- other – any other discomfort (eg. knee, lower back, shin). Please specify.



How to use the pedometer

Your activity monitor contains a computer chip that measures the amplitude and frequency of your movement and determines whether it should count as a step. If your movement should not count, the device adjusts by deducting a step or two from your accumulated "score." Do not let this alarm or discourage you; it is simply how the activity monitor functions to ensure you get an accurate count.

As you may notice, the pedometer also shows the time of day. At midnight, it will automatically 'reset' the current step count and store the previous step count as '1 d'. To access previous days, press the 'Memory' button.

Like any electronic device, water can ruin your pedometer. If you are going to run in heavy rain and it is likely the pedometer may get wet, please do not use, but still complete the activity diary.

The battery supplied should last for 18 months. However, if the battery runs low, a battery icon like the one below will appear at the bottom of the LCD panel. If that happens, contact André to get a replacement.

The mode button will switch between the time and the step count for that day.

To reset the steps, press and hold SET for more than five seconds

The memory button will allow you to see your step count up to the last 7 days.

How to wear

The pedometer clip should be against your body. When you open the case, the screen should face you. To work properly, your pedometer should be worn on your belt or waistband (not in your pocket or loose clothing). Please wear it closer to the side of your body, where your stomach won't interfere (see picture below).

***Date* ____/_____/____** ***Time of start:* _____ am ☐ pm ☐**

(i) For how long did you run? ________minutes

(ii) How many steps did you take? _______steps

(iii) Did you feel any discomfort during the training session? If yes, please complete sections iv and v. Yes ☐ No ☐

(iv) Please mark the lines below to indicate relative discomfort:

	most comfortable condition imaginable	not comfortable at all
overall comfort	|—————————	—————————|
forefoot	|—————————	—————————|
midfoot	|—————————	—————————|
heel	|—————————	—————————|
arch	|—————————	—————————|
fit	|—————————	—————————|
other (please indicate): ____________	|—————————	—————————|

(v) Please comment on what may be the cause (e.g. terrain, weather conditions, insole itself, socks, previous injury or I don't know):

____

Biographical Note

André Siqueira Salles
December 2011

André Salles graduated in Physical Education in Brazil in 2003, when his final project investigated the effects of fatigue on the incidence of fouls and goals scored in professional football. He then moved to United Kingdom in 2004 to study an MSc in Sport and Exercise Science at Manchester Metropolitan University. His dissertation evaluated the effects of countermovement magnitude and volitional effort on vertical jumping performance and was published in the *European Journal of Applied Physiology* in 2011.

After the MSc he worked for a sports consulting company in Brazil for over 2 years, before starting this PhD at Loughborough University as part of the Personalised Sports Footwear research project in January 2008. Andre's research interest include: foot, footwear and orthosis function, comfort and biomechanics; whole body anatomy and anthropometry; and injury in running.