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Development and evaluation of a prefabricated anti pronation foot orthosis

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At a glance.

Development and evaluation of a prefabricated anti pronation foot orthosis

The aim of this work was to develop and evaluate a new anti pronation foot orthosis. Via interviews, clinicians expressed concern that current prefabricated orthoses often did not offer sufficient support to the foot, and orthotic users highlighted issues of durability and hygiene. The geometry of the new orthosis was based on assessment of foot casts and adjusted to enable individual foot size orthoses. The new orthotic material formulated offered high levels of arch support and durability. The orthoisis was tested and found to reduce maximum rearfoot eversion in both walking and running.

Abstract.

Our aim was to develop and evaluate a new anti pronation foot orthosis that addressed problems perceived by clinicians and users with existing foot orthoses. Clinicians and users were engaged to develop a user specification for the orthotic, and orthotic geometry and materials developed using clinical reasoning. The orthotic material properties were tested and the ability of the orthotic to reduce foot pronation evaluated on 27 individuals.

Clinicians expressed concern that current prefabricated orthoses often did not offer sufficient support to the foot due to a combination of shape and materials used, and users concurred but also highlighted issues of durability and hygiene. The geometry of the new orthosis was therefore adjusted to enable individual foot size orthoses to be produced. A material was selected that was harder and more durable than materials used in many prefabricated orthoses. When wearing the new orthotosis maximum rearfoot eversion was reduced in both walking (mean reduction -3.8°, $p<0.001$) and running (mean reduction -2.5°, $p<0.001$). Through a structured process orthotic design decisions were made to address specific concerns of clinicians and users, and the new orthosis has been proven to reduce rearfoot pronation.

Introduction:

The clinical objective of most foot orthoses is to reduce foot pronation that clinicians associate with a range of musculoskeletal problems (e.g. Castro-Méndez et al 2013, Barton et al 2011). Despite poor reliability of the necessary measurements (Jarvis et al 2012, Carroll et al 2011, Lee et al 2012) orthoses customised to the shape of the individual user's foot are still considered the gold standard. However, prefabricated orthoses, that are made without tailoring the orthotic geometry to the patient's foot shape, are a fraction of the cost of custom orthoses and appear to have comparable outcomes, or at least better outcomes may not be proportional to the additional cost (Pfeffer et al 1999, Redmond et al 2009, Landorf et al 2006, Paton et al 2012, Richter et al 2011). The work described in this paper was initiated because whilst prefabricated orthoses are in greater demand due to constraints on health care resources, anecdotal observations by clinical colleagues indicated that there were shortcomings in their design compared to custom made foot orthoses. These included inappropriate arch height and low durability of materials. In addition, the process by which the shape of a prefabricated orthosis had been determined, a critical feature of custom made orthoses, and the rationale for the choice of materials was generally unknown. Finally there was little evidence of the effect of many prefabricated orthoses on foot pronation.

This paper describes the development and evaluation of a new prefabricated foot orthosis undertaken as part of a UK Government scheme (*Knowledge Transfer Partnerships*) to transfer knowledge into the health care industry. The aim of this paper is to: (1) report the development of a prefabricated foot orthosis that sought to address shortcomings of existing prefabricated orthotic devices; (2) to characterise the material properties of the new orthosis and its effect on foot pronation.

Method:

The project comprised three stages: (1) development of orthosis specification; (2) development of orthotic geometry and material (3) evaluation of orthotic materials and the effect on foot pronation. Ethical approval for all stages of the project was obtained from the institutional ethical review board. Participants involved at all stages provided informed consent to participate.

Stage 1: Development of the foot orthosis specification

To develop a specification for the new orthosis, a wide range of existing prefabricated orthoses were appraised through semi structured interviews with: local clinicians who regularly prescribed foot orthoses in public and private health sectors; specialist outdoor and running retailers; and orthotic users (accessed via retail stores and University clinics). The benefits, adverse effects, good and bad features of different foot orthoses were discussed. Information was captured through written notation and thematic analysis. Seven issues were identified (Table 1). Professionals tended to focus on issues related to biomechanical function and orthotic features that were valued in custom made orthoses but absent in prefabricated orthoses, such as orthotic geometry (e.g. arch height, heel cup), and the mechanical support offered by the orthosis material. Retailers and users commented on issues related to symptom relief, durability, and value, but also biomechanical function (support for the foot arch).

Based on the outcomes of the interviews the aim of the subsequent development stages was to develop a prefabricated foot orthosis:

1. made to specific foot sizes;

2. with a medial arch profile tailored for each foot size;

3. that comprised a material that offered a high degree of support for the medial foot arch

4. that was likely to retain its functional properties (geometry and material properties) for extended periods.

5. That reduced the risk of harbouring sweat and dirt and thus odour

Making an orthotic for each foot size, and adjusting medial arch height accordingly, was thought to allow a better match to foot shape than the current use of small-medium-large sizing that each cover 1.5 to 2 shoe sizes. This might also allow for use of a more rigid material because a narrower range of foot shapes would be using each size of orthotic. Subsequent work (stage 2) sought to identify a model foot upon which to determine the orthotic geometry and to identify a material that was suitable for prefabrication manufacturing processes. The material was also to be comparable to materials widely used for custom orthotics in terms of support for the foot, and ideally equally or more durable than materials used for custom orthoses. We decided not to use a top cover in order to reduce risk of harbouring sweat. This also reduced the risk of orthotic materials becoming loose. To further improve hygiene of the orthotic, we sought to identify a material that could withstand repeated exposure to water and thus enable the orthotic to be easily cleaned.

Stage 2 - Development of orthotic geometry and material

Orthotic geometry:

To identify a model foot shape for the new foot orthosis, 80 existing pairs of foot casts taken by one Podiatrist (>30 years orthotic experience) were reviewed. All casts were from patients prescribed custom anti-pronation foot orthoses and had been taken with the patient prone, allowing the foot to hang in a relaxed posture. The only cast modification was addition of plaster to the forefoot to align the heel perpendicular to the supporting surface and ensure a flat surface across the five metatarsals, and minimal graduating of the adjusted forefoot area to the distal aspect of the midfoot. These cast modifications had all been made by the same Podiatrist.

The casts were qualitatively ranked by the Podiatrist who had taken the casts and the review process independently monitored by the principal researcher to ensure consistent reasoning. The aim in this ranking process was to select a single cast toward the median of the 80. Casts with evidence of subluxation or gross pes cavus or pes planus were excluded first since these feet were unlikely to be clinically managed using a prefabricated orthosis. Key features used to rank the remaining casts were (all assessed through visual/manual inspection): ratio of heel and forefoot width; ratio of foot length to heel-to ball length; abduction/adduction of the forefoot relative to the rearfoot; plantarflexion/dorsiflexion position of the metatarsals compared to heel; and height and length of medial arch as a proportion of foot length. Casts at the extremes of one or more of these features were excluded to gradually reduce the number of casts. This process identified 12 pairs of casts.

Custom made foot orthoses were manufactured by hand by one Podiatrist for each of these 12 pairs of casts using high density ethylene vinyl acetate (EVA). To explore real world user acceptance each of the six orthoses were then trialled in random order by six symptom free users for one week (in their own footwear). Each was asked to evaluate comfort and fitting of the orthosis in different footwear, report adverse events and overall perceptions. From this process one orthosis was identified as having the most consistent positive reports from users and the corresponding foot cast became the model for the new orthosis. A physical model of the new orthosis was then made by heat moulding EVA material to the selected cast. Key features of the model orthotic were: full length of the foot; creation of a flat underside to facilitate adhesion of orthotic additions; thickness of 3mm across the forefoot and 1mm in the centre of the heel cup to avoid shoe fitting problems; deep sides to the heel cup; extended lateral flange tapered to the 5th metatarsal head; and a chamfer under the medial arch to follow the typical geometry of a shoe upper. The curved shape of the toe box edge (i.e. distal to the toes) was determined by fitting the orthosis in multiple running, outdoor and leisure footwear styles and ensuring the anterior edge was not too long or broad in any style.

A 3D Computer Aided Design (CAD) model of the orthosis geometry was then created by laser scanning the physical model. To adjust the geometry for specific foot sizes the incremental differences in shoe size were reviewed for various running, outdoor and leisure footwear. These dimensions were applied to the orthotic length/width and scaled changes to the rest of the orthosis model applied. However, the thickness of material under the forefoot and heel was standardised across all sizes to avoid shoe fitting problems. The CAD models were then used to create injection moulding cavities for production purposes.

Orthotic material:

The orthotic material had to satisfy various criteria defined in Part 1 of the project. It needed to be stiff in compression so as to control foot motion. However, because the orthosis would be the full length of the foot the material needed to have low bending stiffness, so as to not interfere with toe flexion. In addition, it needed to maintain its properties over the repetitive loading cycles expected during walking and running, and withstand immersion in water during washing.

A thermoplastic elastomer was prototyped in various hardness formulations and the compression stiffness of each subjectively compared to EVA materials used for custom made orthotics. Prioritising the criteria for high compression stiffness to resist foot pronation (Paton et al 2007), subjective inspection identified one material as being comparable to a high density EVA when produced in a depth equivalent to the medial arch height of the new orthotic (~1cm). At the same time, at a depth of 3mm (the depth of the forefoot area of the orthosis) it displayed a bending stiffness that was subjectively judged to be less than most retail footwear, and thus was unlikely to adversely interfere with toe flexion. This material was then tested for its behaviour in the injection moulding manufacturing process, where it is heated to a melted state, injected under high temperature and pressure into aluminium cavities that match the orthotic geometry. The consistency of the material flow into the cavity, surface aesthetics, and its ability to maintain the complex orthotic geometry during cooling were checked through production of 10 test orthoses.

Stage 3: Evaluation of the orthosis materials and effects on foot pronation.

The aim of stage 3 was to (a) characterise the material properties of the orthotic in the context of the desired performance criteria (from Part 1), (b) quantify the effect the foot orthosis on foot pronation.

Material characterisation.

The material was tested to characterise mechanical properties and water and sweat permeability. To produce test pieces of the chosen material suitable for the testing protocols/equipment, 150(l) x 30(w) x 5mm(depth) plaques of the orthotic material were made through injection moulding according to the experimental conditions provided by the material supplier. Testing methods are detailed in table 2.

Results

The orthotic material had a density of 900 kg/m^3, a Shore A (hardness) value of 85, and 37% resilience, meaning it returned 37% or absorbed 63% of the applied energy in testing. After static deformation to 50% of the original thickness (compression set test) 13.5% of the deformation remained after 30 min and 8.5% after 24h. There was greater deformation at 50ºC, with 22% and 17.3% deformation at 30min and 24h respectively. Under the dynamic compression fatigue test, hardness and resilience were changed by no more than 1% after 25,000 loading cycles at 250 kPa, 700 kPa. Remaining deformation was less than 1% at both loads.

The insole material had no water vapour permeability and water absorption. There was no recorded changes in material dimensions post immersion in artificial perspiration solution.

Furthermore, there was no evidence of crack propagation under optical microscope viewing after 150,000 flexion cycles with and without immersion in the artificial sweat solution.

Discussion

The chosen orthotic material had three times the density of commonly used cellular EVA materials (85-300 kg/m^3) but similar resilience (30-55 %) (Camp-Fauli et al 2008, Healy et al 2010). Similar resilience indicates similar energy absorption capacity despite increased density. The material hardness was comparable to high density EVA materials that are used in some custom made orthoses. These are typically considered to be towards the upper range of what is tolerable under the foot, and are considerably harder than the EVA materials used in many prefabricated orthoses.

At standard testing conditions (23 ºC) the orthotic material demonstrated residual deformation (<13.5%) after a single compression to 50% of its thickness, which was better than the most common EVA (11–34%) and polyethylene (13–26%) materials used for orthoses (Camp-Fauli et al 2008, Mata et al 2001) . This indicates an improved ability to maintain its original shape under static loads and therefore better durability. Other cellular materials have even better performance, such as polyurethane (<1.3%) and latex (6%) (Camp-Faulí et al 2008, Mata et al 2001), but these have much lower hardness and thus offer far less support of foot structures. Greater deformation under the 50 ºC condition is explained by the higher fluency of the polymer chains at higher temperatures.

Results for tests that better replicate the real world use of the material, application of 250 kPa-700 kPa at 1Hz, demonstrated very high durability of the material, loosing just 1% of its original thickness after 25,000 loading cycles. Hardness and resilience were likewise

unchanged after this loading. The fatigue resistance of a thermoplastic elastomer material is due to its elastomeric phase which determines rubberlike properties such as elasticity, flexibility, low compression set, etc. In the case of EVA foam, according to Verdejo et al, foam fatigue is due to the compression and recovery processes of the cellular structure which produce a decline in the initial compressive collapse stress (elastic limit) and the consequently softening of the material over time. Furthermore, the absence of any evidence of crack propagation after 150,000 flexion cycles of the material treated with an artificial perspiration solution is further evidence of the high durability.

The orthotic material demonstrated no water absorption and water vapour permeability, similar to those cellular materials with closed cells like polyethylene or EVA foams. This means the material has very low wicking properties and will not retain sweat within the material structure, although it will remain on the orthotic surface. This means that the moisture has to be absorbed elsewhere, by a sock, or the skin, or reside between the sock and orthotic or sock and skin. However, the low water vapour permeability in addition to the high chemical resistance of thermoplastic elastomers means that washing is unlikely to affect material properties and thus the orthotic surface can be kept clean.

Whilst the tests performed allow direct comparison to other materials and conform to accepted industry standards, they do not identify the material properties of the orthotic itself because this is always a combination of the material and the orthotic geometry. However, these properties are complex and variable, depending on many factors, including the shoe in which the orthosis is used and the direction of loading (user specific), and for some parts of the orthotic, the orthotic size.

Overall the material tests suggest the material is comparable to high density EVA material in terms of hardness and resilience, although it has a higher density. Its durability under compressive loads similar to those experienced during in vivo gait was better than typical EVA materials. Low water permeability properties will allow regular washing without loss of orthotic performance but might require other strategies for moisture management in the shoe.

(B) Effect of orthosis on foot pronation

Twenty seven symptom free subjects aged 18-45 were recruited from staff and student population of the University. All had a negative history of systemic musculoskeletal disease (e.g. rheumatoid arthritis, diabetes) and surgery that might affect foot posture and biomechanics. Motion of the heel relative to the leg was recorded whilst subjects walked and ran with and without the orthosis (figure 2) in a standardised New Balance neutral running shoe (Type M536SR New Balance sports shoes, UK). The mid-sole was EVA with a blown rubber outer sole. Four markers were attached to a plastic plate on the lateral side of the leg. Heel motion was captured using a triad of markers screwed into on a plastic disc attached to the lateral side of the heel and protruding through an aperture in the shoe (figure 3). The alignment of the markers was kept consistent between shoe only and shoe plus orthotic conditions by keeping the plastic disc in situ throughout and using a locating pin to position the triad consistently. Additional anatomical markers on the femoral condyles, malleoli, posterior heel and metatarsal head 2 were added during a static trial in the shoes only condition.

Kinematic data was collected using 10 Qualisys ProReflex cameras (100Hz Qualisys AB, Gothenburg, Sweden). Participants walked/ran over 3 AMTI force plates (500Hz, AMTI, Watertown, MA 02472, USA) to detect initial contact and toe off and passed through

infrared timing gates (10m apart, within a 20m long walkway) to measure speed. Self selected walking/running speeds were determined through multiple pre trials and only subsequent trials within 5% of the target speed were accepted. Ten gait cycles were collected in each of the four conditions.

All calculations were conducted using Visual 3D (Visual 3D C-Motion, Inc.). The shank and heel segments were represented by a local coordinative system. The vertical (z) axis of the local shank frame was defined using the knee and ankle centres (midpoints between femoral condyles and malleoli respectively). The anterior/posterior shank axis (y) was perpendicular to a plane defined by the femoral condyle and malleoli markers. The medial/lateral shank axis (x) was perpendicular to the other two shank axes. The heel local frame orientation was set such that in relaxed standing the z (vertical) axis was perpendicular to the floor (XY of global system) and the y (anterior/posterior) axis was perpendicular to x but parallel to the markers on heel and metatarsal 2 in the static trial. The x axis was perpendicular to the other two axes. Joint rotations (heel relative to shank) were calculated using Cardan angles (sequence x, y, z). All data were normalised to 0-100% of stance phase, 0º was the joint position in relaxed standing in the shoe only condition.

A change in the peak eversion of the heel relative to the shank was the primary measure of orthotic effect. The peak eversion angle in shod and orthotic conditions was compared in the walking and running trials using paired t-tests ($p < 0.05$) (SPSS Version 19.0).

Results

There were no differences between kinematic effects for left/right limbs and data for left limb is therefore presented. When wearing the orthoisis maximum rearfoot eversion was reduced

in both walking (mean reduction -3.8°, 95% CI 2.7-5.0°) and running (mean -2.5°, 95% CI 1.3-3.6)(p<0.001). The mean change in the frontal plane rearfoot position during stance is illustrated in figure 4. The reduction in the eversion position was greatest between 10-60% of stance when walking, and between 20-60% for running.

Discussion:

The mean reduction in rearfoot eversion produced by the new orthosis was greater than the effect size calculated through meta analyses of the literature (3.8° vs. 2.1° from Mills et al 2011, and 2.2° from Cheung et al 2011). The reductions in peak everison during running were smaller than walking, we assume because the forces involved are greater and thus the impact of the orthosis on kinematics reduced. In common with other reports, effects were subject specific, and varied in terms of whether they occurred only in the initial phase of stance, or in some cases throughout stance. A critical issue is what change in peak eversion is required to resolve clinical symptoms associated with foot pronation. This has not been clearly defined by prior research. Our study was motivated by current clinical practice that assumes some reduction in eversion is desirable. Since the observed effects are greater than some of those previously reported, if motion change is important, then the new orthosis might be more effective. However, whether the greater reduction in eversion we report is necessary, or still insufficient, is not yet known.

The reported changes in eversion were achieved despite the fact that the geometry of the orthosis was based on a foot that was not in the sub talar neutral position advocated for custom orthoses (Root et al 1977). The poor reliability of sub talar neutral position is well documented (Jarvis et al 2012) as is the fact it is not a position the foot assumes during gait (Pierrynowski et al 1996). Indeed, recent work suggests the static position of the rearfoot may

not strongly affect medial arch shape (Lee et al 2012). Whilst we did not measure plantar loading, the reported changes in eversion must reflect changes in the forces applied to the rearfoot because changes in force are required to produce changes in movement. Changes in external forces applied to the foot should lead to corresponding changes in the opposing internal forces experienced by tissues that might be injured or painful. We assume this is more important than whether the orthotic design relates to or places the foot into the sub talar neutral position.

One limitation of this evaluation is that we used symptom free subjects and did not assess the foot type of those studied. However, whilst specific features of foot motion, such as heel eversion, are associated with some clinical presentations (e.g. patella-femoral pain, Barton et al 2011, Achilles injury Munteanu et al 2011, plantar callus formation, Findlow et al 2012), differences between groups are often small and unsystematic. In other cases, rearfoot kinematics are less implicated than is often assumed (e.g. plantar fasciitis, Wearing et al 2006). Thus foot kinematics of those with symptoms are not unique compared to those without symptoms. Furthermore via their meta analysis Mills et al (2011) reported only 0.17° difference in the reduction in eversion due to orthoses in injured participants compared to non-injured participants. Rodrigues et al (2013) have recently shown that orthotic response was not different between those with and without anterior knee pain. Finally, the frontal plane rearfoot kinematics of our participants are a good match to those with symptoms in terms of both temporal characteristics of rearfoot motion and values of peak eversion (Rodrigues et al 2013, Barton et al 2011, Munteanu et al 2011, Findlow et al 2012). Nevertheless, it is the case that some feet might exhibit a static or dynamic shape and movement profile that means there is little potential for a prefabricated orthosis to reduce rearfoot eversion as intended. For example, if the foot medial arch is very high and unlikely to contact the arch geometry of an

orthosis, the orthosis is unlikely to have any effect on foot motion. Our sample might include individuals with such feet, although the implication is that the results therefore underestimate the reduction in rearfoot eversion that might be achieved in more suitable feet (i.e. 'pronators').

Discussion

The objective of this project was to design a prefabricated foot orthosis that reduced foot pronation and this was achieved. Prefabricated orthoses typically span 1.5-2 foot sizes and therefore might easily produce an ineffective and/or uncomfortable interface between orthotic and the plantar surface. Our assumption was that the materials used in many prefabricated orthoses were chosen because the materials will quickly deform if the match between foot and orthotic geometries is poor. This avoids the orthoses becoming uncomfortable but compromises its ability to affect external loading of the foot and foot motion. By adjusting the orthotic geometry for each foot size we were able to implement a harder material and avoid this difficulty.

Developing a washable orthosis that did not wick sweat was our solution to hygiene issues raised by users. We achieved very low water penetration, which might imply limited harbouring of bacteria and that repeated washing will not affect orthotic performance. These both seem positive attributes from a hygiene perspective. However, this poses a new problem of moisture management. Any device intended to retain foot sweat should be washable since long term retention of sweat might promote bacteria growth, risk of infection, and odour. Socks rather than insoles/orthotics would therefore seem a more suitable method to manage foot moisture.

Previous evaluations of foot orthoses typically offer only limited information on material properties and orthotic geometry. It is thus difficult to accurately define in mechanical terms the orthoses tested. Often the mode of manufacture (e.g. customised or prefabricated) is reported, but this is meaningless in terms of dynamic biomechanical behaviour of the device since neither the actual geometry nor material properties are known. To our knowledge, this is the first report detailing the development process for the foot orthosis geometry and simultaneous characterisation of material properties.

There are limitations to the work presented here. Firstly, the effect of a foot orthosis is highly specific to the geometry of the upper, lower and side surfaces (the load bearing surfaces), the dynamic behaviour of the materials, the footwear worn (since this influences the forces applied to the orthosis, and the dorsal surface of the foot), and the gait of the user (and users were symptom free). Thus, the effects described here are limited to the device tested and would only be transferable to foot orthoses of a very similar geometry and material composition (Mills et al 2011). Secondly, we did not compare the new orthosis directly to other orthoses. However, published meta analyses on the effect of othoses on rearfoot eversion arguably provides a more valid comparator for the new orthosis, since it includes a far wider range of orthotic designs than could be realistically tested in an experiment (19 orthoses in Mills et al 2011, 13 in Cheung et al 2011). Thirdly, the selection of foot casts and thus orthotic geometry was based on subjective clinical judgement. We would argue this subjective selection was no worse that the well reported variation in clinical assessment of the foot and ankle (Jarvis et al 2012). Risk of inappropriate selection of a model cast was reduced by enabling user feedback to guide the selection of the final orthotic shape. Finally, we did not evaluate plantar pressure changes when using the orthosis, which might help explain the kinematic response. This was not the focus of the evaluation at this stage, but subsequent

research is investigating how changes in orthotic geometry affects plantar soft tissue loading and plantar pressure distribution, and whether these effects explain the scale of, and inter-user variability in, kinematic response.

In summary, we aimed to develop and evaluate an anti-pronation foot orthosis that addressed perceived compromises between customised and prefabricated foot orthoses. Through a subjective but structured process orthotic geometry was derived and a suitable material selected. The orthosis was made in specific foot sizes and using harder and more durable materials than in most prefabricated orthoses. The orthotic reduced rearfoot everison more than recent meta analyses suggest for existing orthoses. The project was intended to transfer knowledge from academia to industry and the orthotic developed was subsequently commercialised, with in excess of 40,000 pairs now in use in the UK and Ireland.

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	Issues	Explanation
1	The arch profile of many prefabricated orthoses is too low	This prevents appropriate control of rearfoot motion and does not support the joints of the medial arch.
2	Little or no heel cup.	This can allow some feet to slide laterally off the orthosis, potential lack of control of heel motion.
3	The materials used in the medial arch area are too soft.	The materials provide insufficient resistance to the downward motion of the medial arch and the eversion motion of the heel
4	Over time prefabricated insoles lose their shape	The ability of the orthosis to influence foot pronation is short lived, the perceived value is low even if the initial effect is good.
5	Top covers or other components can become loose or tear	Layers of orthotic material separating can cause skin irritation, interfere with the fit of the orthosis in the shoe, and make it uncomfortable.
6	Top covers can harbour bacteria and dirt.	Harbouring bacteria and dirt by wicking sweat can encourage a foul odour to develop and adversely affect foot hygiene.
7	Prefabricated orthotics are often made in limited sizes ranges (i.e. S/M/L/XL) and thus a single orthotic geometry is intended to provide suitable contact under the foot across 1.5-2 shoe sizes.	Attempting to fit an orthosis across multiple foot sizes can result in a poor fit to the foot, the footwear and require the orthotic to be manually trimmed. Use of compliant materials for the orthotic is the typical solution to the potential poor fit and reduces the risk of associated skin irritation. However, this material then offers too little support of the rearfoot and medial arch to influence foot pronation.

Table 1: issues with existing prefabricated foot orthoses.

| Material property	Method and experimental description
Apparent density	Standard ISO 845:1988 The ratio of weight to volume expressed in kg/m^3.
Hardness	Standard ISO 7619-1: 2011 The degree of penetration of the material by a standard tool under specified conditions was measured. A hardness meter Shore A was used. The reading is taken 3s after application of the load. Tests pieces were 12 mm thick.
Resilience	Standard UNE 53604:1990 The energy absorption capacity (expressed as % of the energy applied that is returned), tested using a modified Schob pendulum (model 645; Instruments J. Bot. S.A, Barcelona, Spain). Impact energy of 0.2 J was used. Test pieces: 12 mm thickness.
Compression set (static method)	Standard EN ISO 1856:2001/A1:2007 The ability of the material to maintain its elastic properties after a single compression to 50% of its original thickness (conducted at 23 ºC and 50ºC for 22h). The remaining deformation is measured 30 min and 24 h after releasing compression and the results is expressed as a percentage regarding the original thickness. Test pieces: 29 mm diameter, 12 mm thickness.
Compression fatigue test (dynamic method)	Standard UNE 59536: 2007 The remaining deformation of the material after repetitive compressive loads (250KPa, 700KPa) at 1 Hz over 25,000 cycles (Compression Fatigue Test Machine, model 5049, MUVER, Petrer, Spain). Measures were taken 30 min and 24 h after the end of the fatigue process. Test pieces: 29 mm diameter, 10 mm thickness.
Water vapour permeability	Standard EN ISO 14268:2003, method C The amount of water vapour that flows through the material when it is subjected to a vapour-saturated atmosphere in a closed setting, using distilled water at 32ºC for 8 h, expressed in $mg/cm^2·h$. A permeabiliter (Type CTC; Renaud Electronique, France) was used. Test pieces: 29 mm diameter, original thickness.
Perspiration resistance	EN 12801:2001 The ability of the material to resist an artificial perspiration solution, measured as the variation in size (e.g. shrinkage, expansion) post immersion. Five successive ageing cycles were undertaken. Each cycle comprised: 1) Perspiration immersion at 35ºC for 24h; 2) distilled water washing and drying in an oven at 40ºC for 24 h; 3) conditioning at 23ºC and 50% relative humidity for 24 h.
Flex resistance	UNE 59532: 1994 The propagation of cracks in the material post 150,000 flexion cycles (1Hz) post immersion in artificial sweat)

Table 2: Material tests.
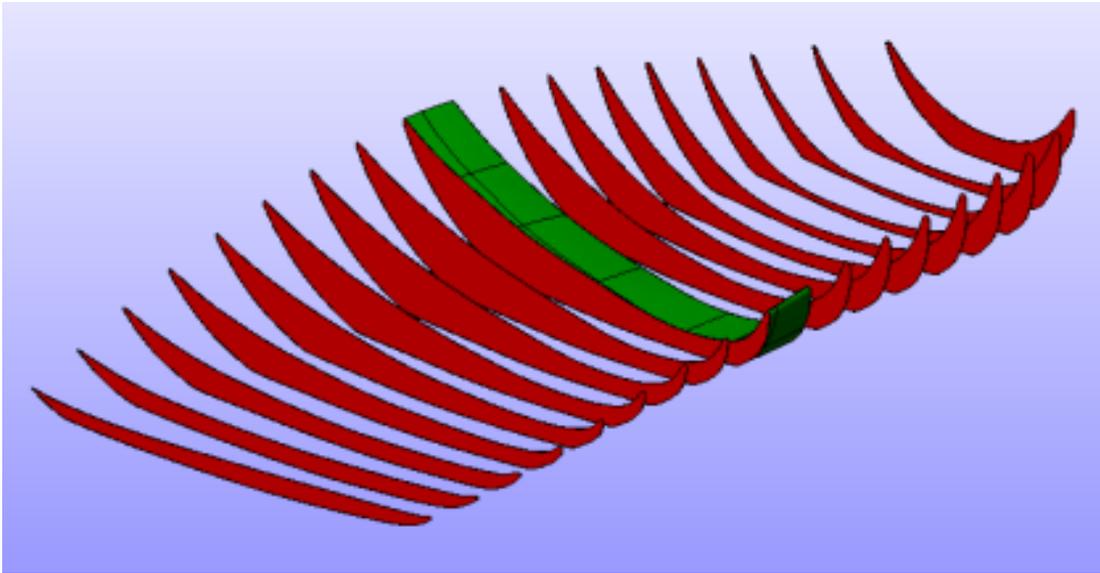
Figure 1: frontal plane cross section geometry of the rear and mid foot parts of the orthotic (left foot)
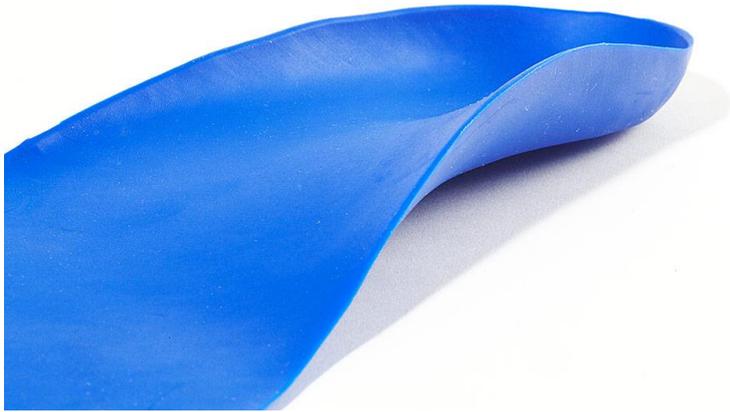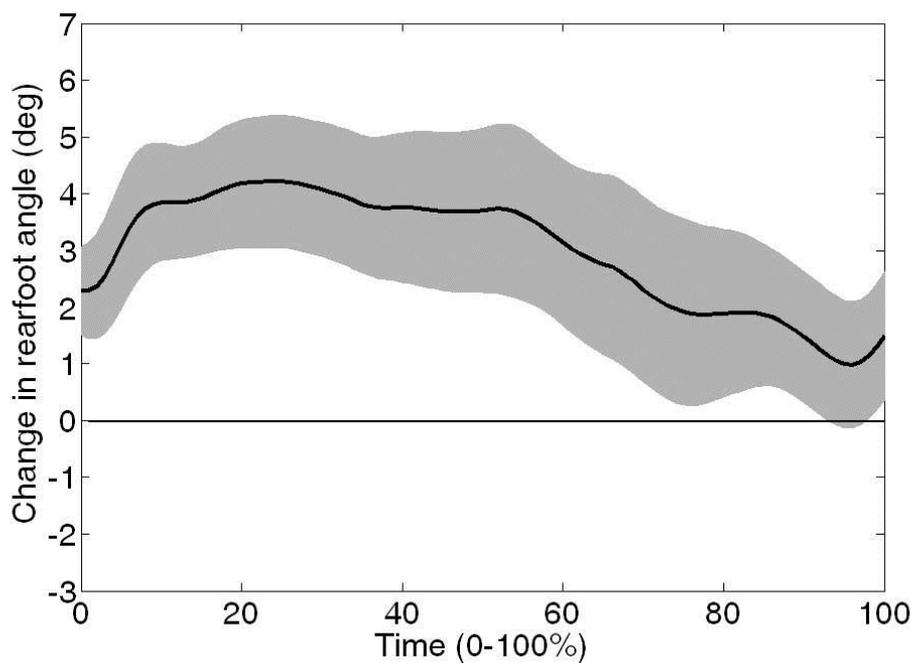
Figure 2. The orthotic manufactured in the chosen thermoplastic elastomer

Figure 3: Three markers mounted on a metal triad, attached to the lateral heel via an aperture in the heel counter threaded onto a rigid plastic base that was taped to the lateral heel.
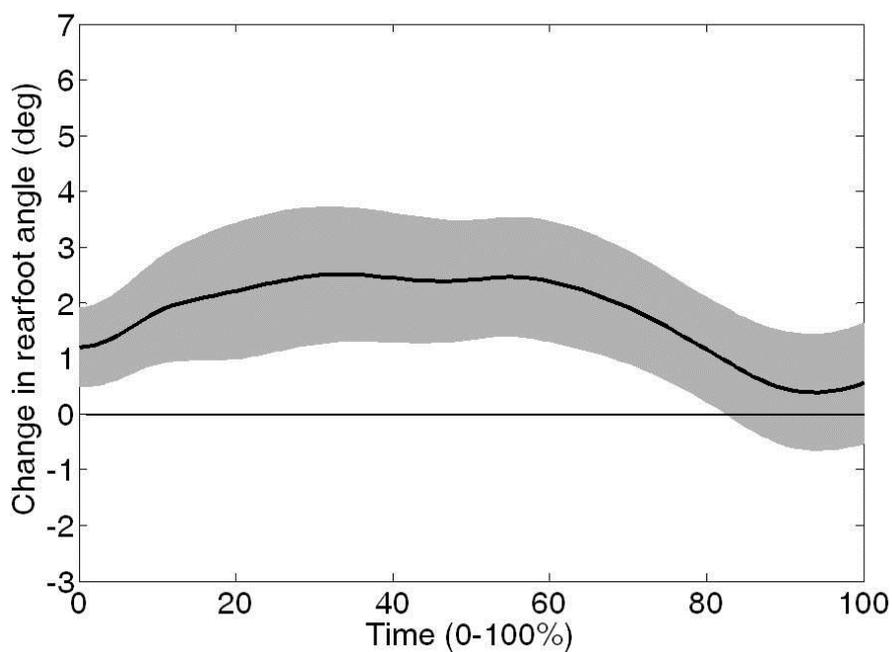
WALK

RUN

Figure 4:
Mean change in frontal plane rearfoot angle (+/-95% CI) when wearing the orthosis. +ve angles indicate a more inverted position, or less everted position, when wearing the orthosis. Walking = solid line, Running = dashed line.