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(54) Title: AN INSOLE FOR AN ITEM OF FOOTWEAR

(57) Abstract: An insole for an item of footwear is provided, the insole comprising an upper surface having a mid-portion underlying the longitudinal arch of the foot of a user, the mid-portion having a medial region, the medial region of the mid-portion of the upper surface having a first coefficient of friction, the remaining regions of the upper surface of the insole having a second coefficient of friction, the first coefficient of friction being greater than the second coefficient of friction. There is also provided an orthopaedic insole for an item of footwear for a diabetic user, the insole comprising a heel portion for underlying the heel of the foot of the user; and a mid portion for underlying the longitudinal arch of the foot of the user; wherein the thickness of the mid portion across the width of the longitudinal arch of the foot of the user is greater than the thickness of the heel portion.
AN INSOLE FOR AN ITEM OF FOOTWEAR

The present invention relates to an insole for an item of footwear. In particular, the present invention relates to an insole for use by a subject suffering from diabetes.

The occurrence of diabetes in the human population is a major health issue. For example, it is estimated that there are approximately 2.8 million diabetics in the UK. It is also estimated that a further 0.85 million people suffer from diabetes, but are not currently diagnosed. Similarly, it is estimated that 25.8 million people in the United States of America suffer diabetes, of which only 18.8 have been properly diagnosed.

A particular issue arising with diabetes is ulceration of one or both feet of the subject, arising due to the diabetic condition reducing the ability for the tissue of the foot to heal properly after being damaged. It is estimated that at any one time, 15% of all diabetics are affected by ulceration of one or both feet. It would be of significant advantage and assistance to diabetics if the occurrence of foot ulcers could be reduced or removed.

Sufferers of diabetes may be divided into two general classes: those with associated neuropathic disorders; and those with vascular disorders. The gait of the diabetic varies according to the type of disorder. Those diabetics with vascular disorders tend to have a gait involving a shuffling motion, giving rise to increased rubbing during motion. The occurrence of neuropathic disorders in diabetics leads to sufferers having a gait in which the foot is stamped, giving rise to high forces being applied to the foot upon impact with the ground. Diabetic neuropathic patients also exhibit a prolonged contact time when walking, which can be more than double the gait cycle duration for a normal gait. This in turn leads to higher pressures on the foot and increased loading times. These factors, in combination with higher shear stresses, result in an increased rate of the formation of ulcers at the heel and forefoot.
Arrangements and constructions for insoles for footwear have been investigated extensively, with a wide range of different insole assemblies and forms having been proposed in the prior art.

For example, US 4,633,598 discloses an insole for a shoe, in particular for use by athletes. The insole comprises an upper layer, a lower layer laminated on the under side of the upper layer, and a layer of shock-absorptive foam material laminated on the under side of the lower layer, at least in the region of the heel of the user.

An orthotic shoe insert is described and shown in US 5,058,585. The shoe insert has a curved wedge of a hook-like shape, when viewed from above, including a heel portion to engage and hold the sides of the heel of the wearer. A middle portion is provided to engage the plantar side of the medial portion of the longitudinal arch of the foot of the subject, and a front portion engages the plantar side of the foot to a level just distal of the first and second metatarsal heads. The insole is alleged to control foot motion to reduce trauma to the lower extremity of the foot and to increase the efficiency of the gait of the user.

US 6,163,983 discloses an insole with an opening. The insole is provided with a sole element on its underside formed from an energy absorbing material. The sole element extends through an opening in the insole and projects above the upper surface of the insole, to form a load transfer region.

US 5,933,984 is concerned with an insole construction for shoes, in particular athletic shoes. The insole construction has a shell portion for extending under the heel and midfoot. Low friction material is provided on portions of the upper surface of the insole. The shell portion is cupped to form a wall along the lateral side of the foot some behind the heel or calcaneus region of the foot. The cupped region provides comfort and load distribution during running.

An orthotic system is disclosed in US 6,038,793. The system comprises a combination partial insole having a heel cup, a midfoot support, a longitudinal arch
support, and a metatarsal pad. Each of the components are designed to control the
motion of the foot of the user during gait and to attenuate shock to the foot.

GB 2,358,121 discloses a foam insole. The insole comprises a compression
moulded foam layer having at least one region of a higher density foam and at least
one region of a lower density foam. The lower density foam may be provided in a
forefoot region, a heel region and/or an arch region.

An orthotic insert for improving the toe-off action of the human foot is
described and shown in US 2002/0133109. The insert is intended for improving the
gait of a person suffering from diabetes, rheumatoid arthritis, or other condition that
impairs the proper transfer of weight to the forefoot when walking. The insert
comprises a rigid cap member having a downwardly extending, transverse ridge
positioned proximate the junction between the arch and the forefoot regions of the
insert, so as to be behind the metatarsal head region of the foot of the user. The
ridge engages with the underlying insole of the shoe and forms a pivot, about which
the insert is able to rock, thereby tilting forwardly and rearwardly during movement of
the foot.

US 6,481,120 discloses a removable insole for insertion into footwear. The
insole is intended for use by persons suffering from arthritis or diabetes. The insole
comprises a forefront portion extending at least to the metatarsals of the foot and
having a bottom layer of shock absorbing, resilient material and a top layer of slow
recovery material to absorb shear forces and to spread out shear forces along the
forefront portion. The insole is further provided with a cupped heel portion having a
flat central portion and a sloped side wall. The insole further comprises a mid-foot
portion having a medial arch support.

US 2004/0159015 discloses an insole for a shoe, the insole having an upper
layer and a lower layer. The lower layer is provided with perforations therethrough
distributed in a grid-like fashion. The upper layer is of a non-perforated, moisture-
wicking, low friction fabric. The insole is said to combine shock cushioning, heat
dissipation, moisture removal and friction reduction.
A shock absorbent footwear assembly is shown and described in US 6,519,874. The assembly has a footbed and an insole removably secured to the footbed. The footbed has a rear portion provided with a cavity adapted to receive a layer of cushioning material.

US 2006/0086004 provides a moulded foot support having a rear portion with a concave periphery for receiving the heel of a user. A cushioning top layer may be provided on the moulded support. It is envisaged that the support may be custom formed to the foot of a user.

US 7,047,667 discloses a composite insole having a bottom layer of open cellular, resilient material and a natural pile top layer. The layers are laminted by heat sealing, by gluing or using a binder, so as not to impede the flow of air through the layers.

A cushioning insole is also described and shown in US 7,107,704. The insole has a non-springy, acceleration-rate sensitive, viscoelastic cushioning layer. An upper layer of low-friction, abrasion-resistant, load-distributing material is provided.

More recently, GB 2,429,394 discloses an insole having a wedge form at the heel, so as to raise the heel of the user. The heel portion of the insole may be formed from several layers, with the user selecting the number of layers of material at the heel to suit the heel elevation required. There appears to be no orthopaedic applications for this insole.

The problems associated with diabetes, in particular ulceration of the foot, have been addressed more fully in US 7,418,755. This document proposes an orthopaedic walking boot for diabetic sufferers, designed to promote rapid healing of foot ulcers by lowering the peak pressure imposed upon the foot. This is achieved by providing the boot with a hard, rigid shell intended for walking, the shell supporting a mid-sole in a foot-shaped bed. The mid-sole has a foot-shaped cavity with rounded sides arranged to form a resilient support for the heel, arch and sides of the foot. The boot is further provided with an inner sole adapted to fit over the foot-shaped cavity and to be compressed in response to pressure applied by the foot. Weight
applied by the wearer to their foot is transferred to the rigid shell by contact between the sides, heel and arch of the foot with the foot-shaped cavity, thereby decreasing the peak pressure applied to the plantar surface of the foot. The boot may be provided with a breathable bootie. It appears that the boot of US 7,418,755 is complex in construction and is difficult to put on and use effectively.

The use of a visco-elastic material to distribute pressure over the insole of a foot of a person has been proposed in US 7,490,419.

Still more recently, an orthopaedic foot appliance providing comfort and shock absorption has been described and shown in US 2009/0094861. The appliance consists of a cushioning insole and a removable support piece.

An insole for a shoe is described and shown in DE 36 00 096. An adjustable shoe insole is disclosed in US 4,813,157. GB 641,078 discloses an insert for an item of footwear.

US 2,246,944 discloses a foot gripper for use in shoes. A metatarsal arch support and grip device is disclosed in US 1,736,827. A foot shank pad is described and shown in US 3,470,880.

An orthopaedic appliance for providing arch support to the foot of a user is disclosed in GB 644,712. An arch support is also disclosed in US 1,163,395. An improved arch support is described and shown in GB 583,683.

An insole formed from polyurethane foam is disclosed in EP 1 602 294.

In general, insoles proposed for use by diabetics are constructed to distribute pressure over the sole of the foot more evenly, in particular using mouldable materials or resilient foams. It is also known to provide material to underlie the heel and metatarsals of the foot to absorb shock, with a view to reducing the peak pressure applied to these regions of the foot. Further, posting at the arch and heel has been used to increase the efficiency of the total contact layer of the insole.
It has now been found that an improved insole may be provided that acts to modify the gait of a user, rather than merely responding to the action of the foot during movement. In particular, it has been found that an insole that acts to correct the deficiencies in the gait of a diabetic in turn reduces the formation of foot ulcers.

In a first aspect, the present invention provides an orthopaedic insole for an item of footwear for a diabetic user, the insole comprising:

a heel portion for underlying the heel of the foot of the user; and

a mid portion for underlying the longitudinal arch of the foot of the user;

wherein the thickness of the mid portion across the width of the longitudinal arch of the foot of the user is greater than the thickness of the heel portion.

It has been found that having the mid portion of the insole underlying the longitudinal arch of the foot significantly thicker than the heel portion acts to modify the gait of a diabetic user. In particular, it has been found that this arrangement encourages the actions of heel strike and toe-off, thus acting to correct deficiencies in the gait pattern of the diabetic. In particular, the arrangement angles the foot during the swing phase of the walking motion, causing the majority of the shock upon impact to travel through the heel upon the heel strike, as in a normal gait. This action, in turn, reduces the overall pressures applied to the foot of the user and the time that pressure is applied to certain regions of the foot, in particular the fore-foot and heel parts of the foot of the user, more especially metatarsal heads. Further, the arrangement reduces the pressure applied to the foot, in particular the metatarsals of the foot, when the user is standing, due to the relative differences in thickness of the heel portion and mid-portion of the insole. As a result, high pressures are only applied to the metatarsal heads during the toe-off phase of the gait. The arrangement also assists in improve the location of the centre of trajectory of the foot during movement, in particular walking. This further aids in distribution of forces across the foot of the user.

The mid-portion of the insole is significantly thicker than the heel portion, in order to provide the aforementioned action in affecting the gait of the user. Preferably, the ratio of the thickness of the mid-portion to the thickness of the heel
portion of the insole is at least 1.5, more preferably at least 1.75, still more preferably at least 2.0. The ratio of the thickness of the mid-portion to the thickness of the heel portion is preferably less than 5.0, more preferably less than 4.0, still more preferably less than 3.0. A ratio in the range of from 1.5 to 4.0 is particularly advantageous, preferably from 2.0 to 3.0. A ratio of from 2.25 to 2.75 is particularly preferred, with a ratio of about 2.5 being advantageous. The preferred ratio may also vary with the size of the insole being fitted. For example, large insoles (for example UK size 10 to 12) preferably have a ratio of about 2.0, medium insoles (for example UK size 7 to 9) preferably have a ratio of about 1.8, and smaller insoles (for example UK size 4 to 6) preferably have a ratio of about 1.5.

The mid-portion may be of any suitable thickness, depending upon such factors as the type and properties of the material of construction, and the end use to be made of the insole. Preferably, the mid-portion of the insole has a thickness of up to 25.0 mm, more preferably up to 20.0 mm. The thickness of the mid-portion may vary with the size of the insole. For example, for larger sizes, the thickness may be up to 20.0 mm, up to 18.0 mm for medium size insoles and up to 15.0 mm for smaller insoles.

The heel portion may be of any suitable thickness, depending upon such factors as the type and properties of the material of construction, and the end use to be made of the insole. Preferably, the heel portion of the insole has a thickness of at least 3.0 mm, still more preferably at least 4.0 mm, in particular at least 5.0 mm. The maximum thickness of the heel portion is preferably 20.0 mm, more preferably 18.0 mm, still more preferably 16.0 mm. A thickness of from 8.0 to 12.0 mm is particularly preferred, more especially from 9.0 to 11.0 mm. A total thickness of about 10.0 mm for the heel portion is preferred for many embodiments.

In a preferred embodiment, the insole increases in thickness longitudinally along the length of the heel portion and the mid-portion in the direction extending longitudinally from the heel end of the insole. Preferably, the insole increases continuously from the heel end of the insole along the length of the heel portion and the length of the mid-portion, more preferably thereby providing the heel portion and the mid-portion with a longitudinal wedge form in vertical cross-section. In this case,
the aforementioned dimensions of the thickness of the heel portion and the mid-
portion refer to the thickness of the heel portion at the heel end of the insole and to
the thickness of the mid-portion at its thickest region.

The mid-portion may be uniform in thickness across its width, that is across
the width of the users foot from the medial side to the lateral side. More preferably,
the mid-portion of the insole is thicker in the medial region than the lateral region.
The mid-portion may be provided in the form of a laterally extending form that is
generally wedge-shaped extending across the width of the mid portion, with the
general wedge form being of a higher thickness at the medial edge of the mid-portion
and a lower thickness at its lateral edge. In one embodiment, the mid-portion is
provided with a portion of increased thickness at its medial edge and extending
across the mid-portion to the central region of the mid-portion. The remainder of the
mid-portion, in particular extending from this central region to the lateral edge is of a
lower thickness and may be uniform in thickness.

In particular, the medial region of the mid-portion may be provided with a
thickness of up to 25.0 mm, more preferably up to 20.0 mm. The thickness of the
medial region may vary with the size of the insole. For example, for larger sizes, the
thickness may be up to 20.0 mm, up to 18.0 mm for medium size insoles and up to
15.0 mm for smaller insoles. The lateral region may have a thickness in the range of
from 10.0 mm to 18.0 mm, more preferably from 10.0 to 15.0 mm. The ratio of the
thickness of the medial region to the lateral region may be in the range of greater
than 1.0 up to 2.5, more preferably up to 2.3. A ratio of greater than 1.0 to about 2.0
is particularly preferred for many embodiments.

The heel portion may be uniform in its thickness across its width from the
medial side to the lateral side. More preferably, the heel portion is provided with a
heal cup, that is a region central to heel portion to underlie the calcaneus of the foot
of reduced thickness compared with the remainder of the heel portion. For example,
the heel cup may be formed as a recess and/or an opening in the insole or a portion
thereof, such as a recess or opening in one layer of the insole, as described below.
If present, the outer region of the heel portion around the heel cup may have a
thickness of from 10.0 to 15.0 mm, preferably about 12.0 mm, while the central
region of the heel cup may have a thickness in the range of from 5.0 to 10.0 mm, preferably about 7.0 mm.

Preferably, the insole further comprises a fore-foot portion for underlying the metatarsals of the foot of the user. The fore-foot portion has a thickness that is also significantly less than the thickness of the mid-portion of the insole. In this way, the heads of the metatarsals of the foot are not forced into contact with the insole when the user is standing and significant pressure is only applied to this region of the foot during the toe-off phase of the gait, as noted above. In addition, this form encourages the user to progress forward and for the foot to leave the ground with the first toe.

Preferably, the ratio of the thickness of the mid-portion to the thickness of the fore-foot portion of the insole is at least 1.5, more preferably at least 1.75, still more preferably at least 2.0. The ratio of the thickness of the mid-portion to the thickness of the fore-foot portion is preferably less than 10.0, more preferably less than 6.0, still more preferably less than 5.0. A ratio in the range of from 1.5 to 6.0 is particularly advantageous, preferably from 2.0 to 5.0. A ratio of from 2.25 to 4.0 is particularly preferred, with a ratio of about 3.5 being advantageous.

The fore-foot portion may be of any suitable thickness, depending upon such factors as the type and properties of the material of construction, and the end use to be made of the insole. Preferably, the fore-foot portion of the insole has a thickness of at least 3.0 mm, still more preferably at least 4.0 mm, in particular at least 5.0 mm.

The maximum thickness of the fore-foot portion is 18.0 mm, more preferably 15.0 mm, still more preferably 13.0 mm.

The fore-foot portion may be uniform in thickness across its width. More preferably, the fore-foot portion is thicker in its lateral region than its medial region.

The difference in thickness between the medial and lateral regions of the fore-foot portion improves the centre of pressure trajectory of the foot of the user during walking. This in turn improves the centre of pressure trajectory of the foot during walking, ensuring the correct forces are transferred and distributed to the appropriate areas of the foot. More particularly, the fore-foot portion has a lateral region of
thickness in the range of from 5.0 to 15.0 mm, more preferably from 6.0 to 13.0 mm, while the medial region is of thickness from 2.0 to 8.0 mm, more preferably from 3.0 mm to 6.0 mm. The ratio of the thickness of the lateral region to the medial region is preferably at least 1.5, more preferably at least 2.0. A ratio of up to 4.0, more preferably up to 3.0 may be employed, as required.

The fore-foot portion preferably has a uniform thickness along its length.

The insole of the present invention may be formed from any suitable posting material to withstand the forces and pressure applied to the insole under the action of the foot of the user during the gait cycle without significant deformation, to thereby act on the foot to provide the aforementioned effects on the gait, in particular to provide sufficient support for the foot, adjust the gait of the user and increase the contact area between the insole and the foot. The material may be any high density foam that may be moulded and formed, for example by sanding or milling. Suitable materials for the insole, in particular foam materials, are known in the art and are available commercially. Suitable materials include ethylene vinyl acetate (EVA), polyurethane, and polyethylene foams.

The posting material may have any suitable density. Preferably, the posting material has a hardness in the range of from 40 to 50D (durometer). A posting material of a hardness of about 40D is particularly preferred.

The posting material is most preferably of a type that allows the shape and thickness of the insole to be modified, for example, by a medical practitioner to allow the insole to be formed to meet the needs of a specific subject and provide the alteration to the gait of the subject as required. In particular, the properties of the material should allow the practitioner to remove material, for example by cutting and/or sanding, to reduce the thickness of the insole in some or all regions thereof.

One particularly suitable posting material for use in the aforementioned insole structure is Evalon®, commercially available from Algeos Limited, UK.
The insole having the aforementioned structure may be formed from a single piece of material or posting. For example the posting material may be cast or milled to provide the required structure and form. Alternatively, the aforementioned structure is a composite arrangement of a plurality of insole components, in particular a plurality of components arranged in a plurality of layers. Some or, more preferably all, of the plurality of insole components are formed from a posting material.

In one embodiment, the insole comprises a first posting component comprising a first posting layer and a second posting layer. The posting layers are formed to be resistant to forces applied to the insole during the gait cycle, thereby acting on the foot of the user in the aforementioned manner to adjust the gait of the user during motion.

The first posting layer extends at least the length of the mid-portion of the insole, more preferably extending the length of the mid-portion and a portion of the heel portion of the insole. The first posting layer may be formed from any suitable material to provide the necessary resistance to the forces applied by the foot.

The second posting layer extends over the first posting layer and extends the length of the heel portion and the mid-portion of the insole. If the heel portion of the insole comprises a heel cup, the cup may be formed in the second posting layer, for example by providing the second posting layer with a recess or an opening therein for accommodating the heel of the user. The recess or opening in the second posting layer may contain a material that is soft relative to the material of the second posting layer, such that the material yields under the force applied to the insole by the foot of the user when in motion.

The first and second posting layers may have any suitable thickness. The thickness of the layers will depend upon such factors as their material of construction, their density and resistance to compression under the action of the foot of the user. Preferably, each of the first and second posting layers has a thickness of from 1 to 5 mm, more preferably from 2 to 4 mm. The first and second posting layers are preferably the same thickness.
The first and second posting layers may be formed from any suitable material. Suitable foam materials are known in the art. The first and second posting layers may be formed from the same or different materials. Preferably, the first and second posting layers are formed from the same material. Suitable materials for use in forming the first and second posting layers are as described hereinbefore. One suitable material for forming the first and/or the second posting layer is Evalon® (commercially available from Algeos Limited, UK).

The materials of the first and second posting layers may have any suitable density. As noted above, the first and second posting layers are required to provide resistance to forces applied to the insole during the action of the foot of the user. The form of the first and second posting layers, in particular the aforementioned longitudinal wedge form, provides the action of the insole on the foot of the user to reduce the peak pressure and pressure duration on the foot and to adjust the gait of the user, when walking. For this reason, the first and second posting layers are formed from relatively high density materials. Preferably, the density/hardness of the material of the first and second posting layers is in the range of from 40 to 50D, in particular about 40D.

The density of the material of the first and second posting layers may be different, but is preferably the same. The first and second posting layers may be combined to form a single layer of posting material.

As noted above, the insole may be provided with a mid-portion that is thicker in its medial region than in its lateral region. To achieve this form, the insole may be provided with one or more layers of posting material at its mid-portion, in particular in an upper region of the mid-portion. For example, the insole may be provided with a first mid-portion posting layer and a second mid-portion posting layer extending over the first, the first and second mid-portion layers extending across at least the medial region of the mid-portion. In one embodiment, the first and second mid-portion posting layers are provided on the aforementioned first and second posting layers, thus providing the medial region of the mid-portion of the insole with four layers of posting material.
The first and second mid-portion posting layers may have any suitable thickness. The thickness of the layers will depend upon such factors as their material of construction, their density and resistance to compression under the action of the foot of the user. Preferably, each of the first and second mid-portion posting layers has a thickness of from 1 to 5 mm, more preferably from 2 to 4 mm. The first and second mid-portion posting layers are preferably the same thickness.

The first and second mid-portion posting layers may be formed from any suitable material. The first and second mid-portion posting layers are preferably formed from a foam material. Suitable foam materials are known in the art. The first and second mid-portion posting layers may be formed from the same or different materials. Preferably, the first and second mid-portion posting layers are formed from the same material. Suitable materials for use in forming these posting layers are as described hereinbefore. One suitable material for forming the first and/or the second mid-portion posting layer is Evalon® (commercially available from Algeos Limited, UK).

The materials of the first and second mid-portion posting layers may have any suitable density. As noted above, the first and second mid-portion posting layers are required to provide resistance to forces applied to the insole during the action of the foot of the user. The form of the first and second posting layers, in particular the aforementioned laterally extending wedge form, provides the action of the insole on the foot of the user to further reduce the peak pressure and pressure duration on the foot and to adjust the gait of the user, when walking. For this reason, the first and second mid-portion posting layers are formed from relatively high density materials. Preferably, the density/hardness of the material of the first and second mid-portion posting layers is in the range of from 40 to 50D, in particular about 40D.

The density/hardness of the material of the first and second mid-portion posting layers may be different, but is preferably the same.

As noted above with respect to the general properties of the material of the insole, the first and second posting layers and first and second mid-portion posting
layers are preferably formed from a material that may be modified in shape by a medical practitioner, so as to allow the insole configuration to be fitted to meet the needs of a specific subject.

The first and second posting layers and first and second mid-portion posting layers are preferably formed from the same material. The aforementioned layers may be provided with any suitable thickness, with the thickness of the layers being the same or different. Suitable thicknesses for the layers are in the range of from 1.0 mm to 10.0 mm, more preferably from 2.0 to 8.0 mm, still more preferably from 3.0 to 7.0 mm. A thickness in the range of from 4.0 to 6.0 mm is particularly preferred for many embodiments. Preferably, the layers are all provided with the same thickness. The layers are preferably provided with a uniform thickness along their length and across their width, such that the aforementioned structures are formed by assembling the layers to overlie one another, with the structure being provided by the number of layers of material varying along the length and across the width of the insole, for example as described hereinbelow with reference to the specific embodiments of the invention.

The insole of the present invention may comprise one or more further layers of material, in addition to the aforementioned structures, in particular one or more layers overlying the aforementioned structures.

For example, the insole may comprise a layer of shock-absorbent material extending over the aforementioned structures. If present, the layer of shock-absorbing material extends across at least the heel portion, more preferably across at least the heel portion and mid-portion of the insole. The shock absorbing material may extend over the fore-foot portion of the insole, if present. In one embodiment, the layer of shock absorbing material extends longitudinally from the mid-portion of the insole across the lateral region of the fore-foot portion.

The shock-absorbing material may be any suitable material to absorb a portion of the forces applied to the insole by the action of the foot of the user. In particular, the layer of shock-absorbing material acts to reduce the high forces transmitted to the foot during the heel strike phase of the gait cycle. The shock-
absorbing material is therefore resilient. Suitable materials include foams. Suitable materials are known in the art and are available commercially. Suitable materials include gels and foams, for example silicone gel, low density ethylene vinyl acetate (EVA) and polyurethanes.

One suitable shock-absorbing material is Poron XRD®, available commercially from Rogers Corporation.

The shock-absorbing layer may have any suitable thickness. Preferably, the thickness of the shock absorbing layer is in the range of from 1.0 to 10.0 mm, more preferably from 2.0 to 8.0 mm, still more preferably from 3.0 to 6.0 mm. A thickness of about 3.0 mm has been found to be suitable for many embodiments.

The material of the shock-absorbing layer is generally of a lower density/hardness than that of the aforementioned posting layers. For example, the shock-absorbing material may have a density/hardness in the range of from 5 to 40 D (durometer hardness), more preferably from 8 to 35 D, still more preferably from 10 to 32 D. A hardness of about 19 D is particularly suitable for many embodiments.

In one embodiment, the insole comprises a layer of memory material extending over the aforementioned structures. In this respect, a 'memory' material is a reference to a resilient material that slowly returns to its original shape after being deformed by the action of the foot of the user, referred to in the art as 'slow recovery' materials. The function of the memory material is to provide a significantly greater area of contact between the underside of the foot of the user and the entire or substantially the entire upper surface of the insole throughout the gait cycle.

The memory material is most preferably provided in the upper region of the insole, that is at or close to the upper surface of the insole. If the insole comprises a layer of shock-absorbing material, the layer of memory material preferably directly or indirectly overlies the shock-absorbing material.

The memory material preferably extends across at least the heel portion and mid-portion of the insole. The shock absorbing material may extend over the fore-
foot portion of the insole, if present. In one embodiment, the layer of memory material extends across the entire fore-foot portion of the insole. The memory material most preferably extends the entire length and width of the insole.

The memory material may be any suitable material to provide the aforementioned action. Suitable materials include memory foams. Suitable materials are known in the art and are available commercially. Suitable materials include gels and foams, for example low and medium density polyurethane foams.

One suitable memory material is Poron 96®, available commercially from Rogers Corporation.

The layer of memory material may have any suitable thickness. Preferably, the thickness of the layer of memory material is in the range of from 1.0 to 12.0 mm, more preferably from 2.0 to 10.0 mm, still more preferably from 3.0 to 9.0 mm. The thickness of the memory material may be lower when a layer of shock-absorbing material is present, for example being about 3.0 mm, and higher when no shock-absorbing material is present, for example about 6.0 mm.

The memory material may have any suitable density/hardness. For example, the memory material may have a hardness in the range of from 40 to 60 D (durometer), more preferably about 50 D.

In addition to the aforementioned structures to reduce the peak pressures applied to the foot, reduce the duration of pressure being applied to key regions of the foot, and adjust the gait of the user, it has been found that the properties of the upper surface of the insole are important in helping to reduce ulceration of the foot, in particular the foot of a diabetic. More particularly, it has been found that it is advantageous if the different regions of the upper surface of the insole are provided with different friction properties. It has especially been found that it is advantageous to provide the medial region of the mid-portion of the upper surface of the insole with a relatively high coefficient of friction, so as to grip the overlying portion of the foot, while providing the remaining regions of the upper surface of the insole with a
relatively low coefficient of friction, allowing the foot of the user to move easily over these regions and thereby reducing the shear forces applied to the foot.

Accordingly, in a further aspect, the present invention provides an insole for an item of footwear, the insole comprising an upper surface having a mid-portion underlying the longitudinal arch of the foot of a user, the mid-portion having a medial region, the medial region of the mid-portion of the upper surface having a first coefficient of friction, the remaining regions of the upper surface of the insole having a second coefficient of friction, the first coefficient of friction being greater than the second coefficient of friction.

The medial region of the mid-portion of the upper surface of the insole is provided with a sufficiently high friction property to grip the foot of the user. It has been found that to hold the foot in position on the insole and prevent the foot slipping in the item of footwear, it is sufficient to provide this region of the upper surface with a high friction property. The remainder of the upper surface may be provided with a low friction property. The high friction region prevents the foot slipping, in turn preventing rubbing of the surfaces of the foot at the sides and at the toes. This arrangement is particularly beneficial for sufferers of diabetes, as the medial region of the mid-portion of the plantar surface of the foot is least likely to develop an ulcer, compared with the regions of the plantar surface at the heel or the metatarsals.

The high friction region preferably extends from the medial edge of the mid-portion in the lateral direction to the centre of the mid-portion more preferably up to two thirds of the width of the mid-portion. Thus, the high friction region preferably extends in the lateral direction at least 50% of the width of the mid-portion, more preferably at least 60%, still more preferably at least 65%.

The high friction region of the upper surface is preferably provided with a coefficient of friction as high as possible, in order to securely grip the foot. The coefficient of friction is preferably at least 1.0, more preferably at least 1.5, still more preferably at least 2.0. A coefficient of friction of at least 2.5, more preferably at least 3.0 is particularly preferred. This high friction surface may be achieved by any suitable means, for example by treatment of the surface of the insole with a high
friction agent. Preferably, the high friction is achieved by providing the said region of the upper surface of the insole with a layer of high friction material. Suitable high friction materials are known in the art and are commercially available. Suitable materials include natural rubbers and polymers, such as synthetic rubbers and gels, for example silicone rubbers and gels.

An example of a suitable material is Ironman rubber (available commercially from Algeos Limited, UK).

The low friction region of the upper surface is preferably provided with a coefficient of friction as low as possible. The coefficient of friction is preferably less than 1.0, more preferably less than 0.8, still more preferably less than 0.6. A coefficient of friction less than 0.5, more preferably less than 0.4 is particularly suitable. This low friction surface may be achieved by any suitable means, for example by treating the surface of the insole with a low friction agent. Preferably, the low friction is achieved by providing the said region of the upper surface of the insole with a layer of low friction material. Suitable low friction materials are known in the art and are commercially available. Suitable materials include natural and synthetic leather and suede, low friction polymers, such as nylon.

An example of a suitable material is leather or natural pigskin. Nylon materials, such as Cambrelle® are also particularly suitable.

The insole is preferably provided with anti-microbial, including anti-bacterial, properties. For example, the upper surface of the insole is preferably impregnated with one or more anti-microbial agents. Suitable agents, such as antimicrobial liquids are known in the art and are commercially available. The presence of silver ions in the insole material also acts as an antimicrobial agent, as is known in the art.

It is further preferred that the upper surface of the insole is able to absorb moisture. For example, leather mentioned above as suitable for use as the low friction surface material also has the property of absorbing moisture from the foot of the user.
A particularly preferred insole comprises the features of the first and second aspects of the present invention described hereinbefore.

In a further aspect, the present invention provides an item of footwear comprising an insole as hereinbefore described. The item of footwear may be a shoe, a boot or the like.

In a still further aspect, the present invention provides a method for adjusting the gait of a subject, the method comprising providing an insole as hereinbefore described in an item of footwear being worn by the subject. The method is particularly advantageous for the treatment of diabetic subjects.

Embodiments of the insole of the present invention will now be described, by way of example only, having reference to the accompanying drawings, in which:

Figure 1 is a cross-sectional view of a mid-portion of an insole according to one embodiment of the present invention;

Figure 2a is a longitudinal vertical cross-sectional view of an insole according to a second embodiment of the present invention;

Figure 2b is a cross-sectional view across the mid-portion of the insole of Figure 2a along the line II B - II B;

Figure 2c is a plan view of the insole of figure 2a;

Figure 3 is a diagrammatical representation of an insole according to a third embodiment of the present invention;

Figures 4a to 4d are plan views of the components of the insole of Figure 3;

Figure 5 is a plan view of the upper surface of an insole according to a fourth embodiment of the present invention;
Figures 6a to 6c are images of pressure distribution on the foot of a patient obtained during static testing; and

Figure 7 is a set of images of pressure distribution on the foot of a patient obtained during dynamic testing.

Referring to Figure 1, there is shown a vertical cross-section through the medial region of the mid-portion of an insole. The insole, generally indicated as 2, has an upper surface 4. The insole 2 comprises a posting layer 6 formed from a high density posting material (Evalon®, ex. Algeos Limited, UK).

The insole 2 further comprises a layer 8 of shock-absorbing material (Poron XRD®, ex. Algeos Limited). A layer 10 of memory foam (Poron 96®, ex. Algeos Limited) overlies the layer 8. The medial region of the mid-portion of the insole 2 is provided with a layer 12 of rubber (Ironman Rubber, ex. Algeos Limited) to provide this region of the upper surface 4 with sufficient grip to hold the foot of the user in place on the insole and prevent movement of the foot across the upper surface of the insole. The remaining regions of the insole 2 are provided with a layer 14 of leather, providing the upper surface 4 with a low friction property.

The upper surface 4 of the insole 2 is treated with a commercially available anti-microbial agent (Microfresh, ex. Buffalo Leather).

A further embodiment of an insole of the present invention is shown in Figures 2a to 2c. The insole is shown in cross-sectional and plan views. The insole is shown as a single layer of posting material.

A longitudinal cross-section of the insole is shown in Figure 2a. The insole, generally indicated as 102, has a heel end 104 and a toe end 106, and comprises a heel portion 108, a mid-portion 110 and a fore-foot portion 112. The insole 102 comprises a layer 114 of high density posting material (Evalon®, ex. Algeos Limited, UK). As shown in Figure 2a, the layer 114 is formed with a longitudinal wedge 116.
extending from the heel end 104 along the heel portion 108 in a distal direction to the
distal end 118 of the mid-portion 110.

The heel end 104 of the insole has a thickness of 6.0 mm. The mid-portion
110 at its thickest has a thickness of 15.0 mm. The fore-foot portion 112 of the
posting layer 114 is shown as having generally the same thickness as the heel end
104 of the insole.

As shown in Figure 2b, the mid-portion 110 is provided with a non-uniform
thickness across its width. In particular, the mid-portion 110 has a medial edge 120,
a central region 122, and a lateral edge 124. As shown in Figure 2c, the mid-portion
is provided with a region 126 extending from the medial edge 120 to the central
region 122, the region 126 having an increased thickness and formed with a convex
upper surface 128. As further shown in Figure 2b, the remaining regions of the mid-
portion have a uniform thickness extending from the central region 122 to the lateral
edge 124.

The thickness of the various regions of the posting layer may be adjusted
according to the needs of the subject, in order to provide the required adjustment to
the gait of the subject.

Figures 2a and 2b show only the posting layer of the insole. The insole 102
of Figures 2a and 2b may be provided with one or more of the further layers of
material shown in Figure 1 and described above. In particular, the insole 102 is
preferably provided with a layer of leather and a rubber grip portion, arranged as
described in more detail below and shown in Figure 5.

Referring to Figure 3, there is shown a diagrammatical representation of an
insole according to a third embodiment of the present invention. The insole,
generally indicated as 202, is shown in Figure 3 in plan view. The insole as shown in
the figure comprises a plurality of layers of posting material, which are indicated in
the assembled form in Figure 3. In order from the bottom of the insole to the upper
surface of the insole, as oriented in use, the insole 202 comprises a first bottom
posting layer 204, a second bottom posting layer 206, a first top posting layer 208
and a second top posting layer 210.

The insole 202 shown in Figure 3 comprises a heel portion 212, a mid-portion
214 and a toe portion 216.

Each layer 204 to 210 of posting material is shown individually in Figures 4a
to 4d, details of which are as follows:

The first bottom posting layer 204 is shown in Figure 4a, and has a distal end
218 oriented towards the toes of the foot of a user when in use and a proximal end
220 underlying a portion of the heel of the foot of the user. The first bottom posting
layer 204 is located as shown in Figure 3 and extends the full length of the mid-
portion 214 of the insole 202.

The second bottom posting layer 206, shown in Figure 4b, overlies the first
bottom posting layer and comprises a distal end 222 and a proximal end 224, the
layer 206 having therebetween a heel portion 226, a mid-portion 228 having a medial
region 228a and a lateral region 228b, and a fore portion 230. The heel portion 226
is formed with a generally 'P' shaped opening 232 extending from the medial edge
234 of the layer 206. The opening 232 provides the insole with a cup for
accommodating the heel of the foot of the user, when the insole layers are
assembled. The fore portion 230 of the layer 206 extends in a distal direction from
the lateral region 228b of the mid-portion 228 and underlies the metatarsals of the
foot of the user to the lateral side of the centre of the foot.

The first top posting layer 208, shown in Figure 4c, overlies the medial region
228a of the mid-portion of the second bottom posting layer 206 and has a distal end
236, a proximal end 238, a medial edge 240 and a convex arcuate lateral edge 242.

The second top posting layer 210, shown in Figure 4d, overlies the first top
posting layer 208 and has the same general shape and configuration as the first top
posting layer, but with reduced dimensions, such that the second top posting layer
lies within the edges of the first top posting layer, with their medial edges aligned.
The posting layers 204, 206, 208, 210 are formed from the same material, in particular Evalon® (ex. Algeos Limited, UK). The posting layers 204 to 210 are each formed with a uniform thickness along their length and across their width, in particular a thickness of 4.0 mm.

It is to be appreciated that the structure formed by the posting layers 204, 206, 208, 210 may also be formed as a single layer of material, for example by moulding, milling and/or sanding.

Figures 3 and 4a to 4c show only the posting layer of the insole. The insole of these figures is preferably provided with one or more of the further layers of material shown in Figure 1 and described above. In particular, the insole is preferably provided with a layer of leather and a rubber grip portion, arranged as described in more detail below and shown in Figure 5.

Turning now to Figure 5, there is shown a plan view of an insole according to a further embodiment of the present invention, the insole generally indicated as 302. The insole 302 has a heel end 304, a toe end 306, a heel portion 308, a mid-portion 310 and a fore-portion 312. The insole has a medial edge 314 and a lateral edge 316. The insole 302 further has an upper surface 318 formed by the top layers of the insole. The medial region of the mid-portion is provided with a layer 320 of rubber (Ironman rubber, ex. Algeos Limited), extending from the medial edge 314 laterally across the mid-portion generally to the centre or up to two thirds of the width of the insole mid-portion 310. The remainder of the upper surface 318 of the insole is provided by a layer 322 of leather (ex. Algeos Limited). The leather is treated with an anti-microbial agent as known in the art.

In use, the layer 320 of rubber at the medial region of the mid-portion acts to grip the foot of the user, in particular in the region of the arch of the foot. This is sufficient to keep the foot in location on the upper surface of the insole and to reduce or prevent movement of the foot across the insole, during use. The surface of the layer 322 of leather has a low coefficient of friction, over which the foot could easily move, if not held by the rubber grip portion. This arrangement is particularly useful.
for insoles intended for diabetic subjects. The rubber grip portion is limited to that region of the foot that provides the greatest action in holding the foot, thereby keeping the area of the rubber portion to a minimum. This in turn maximises the area of the upper surface that is provided by the low friction leather material. This arrangement is particularly beneficial in reducing the formation of ulcers on the foot of users, in particular diabetic subjects.

EXAMPLE

Experiments were conducted as follows to the test the efficacy of the insole of the present invention.

Experimental Procedure

A batch of insoles (hereinafter designated as Insoles A) was prepared, each insole having the construction shown in Figures 1, 3, 4a to 4d, and 5 and described above.

The insoles were provided to 16 patients with diabetes for both static and dynamic testing. The distribution of the pressure applied to the foot of the patient was measured using a PodoTech pressure plate (ex. Algeos Limited, UK). In the static tests, the patient stood on the pressure plate. In the dynamic tests, the patient stepped onto the pressure plate in the course of their normal gait cycle as part of a walk of 5 m length.

For comparison purposes, the same experimental procedures were followed by the patients in two further tests: a) without wearing insoles; b) wearing standard contact insoles (hereinafter designated Comparisons A). The standard contact insoles (Comparisons A) were the insoles provided for the patient and generally comprised a base layer of ethylene vinyl acetate (EVA) with a layer of memory foam thereover.
During the experiments, parameters of the pressure applied to the foot of the patients relevant to the formation of ulcers in diabetic patients were measured.

Results

a) Static Tests

The results of the static tests are set out in Tables 1 and 2 below.

Table 1: Comparison between Insoles A and no insoles

<table>
<thead>
<tr>
<th>Variable</th>
<th>Change monitored</th>
<th>Number of patients experiencing benefit (%)</th>
<th>Average beneficial change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak Pressure</td>
<td>Reduced Pressure</td>
<td>69</td>
<td>27</td>
</tr>
<tr>
<td>Peak Pressure at Metatarsals</td>
<td>Reduced Pressure</td>
<td>94</td>
<td>42</td>
</tr>
<tr>
<td>Peak Pressure at Heel</td>
<td>Reduced Pressure</td>
<td>69</td>
<td>24</td>
</tr>
<tr>
<td>Total Contact Area of Foot</td>
<td>Increased Contact Area</td>
<td>75</td>
<td>19</td>
</tr>
<tr>
<td>Total Contact Area of Metatarsals</td>
<td>Reduced Contact Area</td>
<td>59</td>
<td>16</td>
</tr>
<tr>
<td>Total Contact Area at Heel and Arch</td>
<td>Increased Contact Area</td>
<td>88</td>
<td>49</td>
</tr>
<tr>
<td>Y – Coordinate of the Centre of Pressure</td>
<td>Movement of Centre of Pressure Closer to Heel</td>
<td>66</td>
<td>6</td>
</tr>
</tbody>
</table>

As can be seen from the data in Table 1, Insole A reduced the peak pressures applied to the foot of the patient. In particular, the peak pressure applied
to the metatarsal region of the foot was significantly reduced. As this region is a region of the diabetic foot particularly vulnerable to ulceration, this improvement is significant in maintaining the health of the feet of diabetic patients.

Table 2: Comparison between Insoles A and Comparison A

<table>
<thead>
<tr>
<th>Variable</th>
<th>Change monitored</th>
<th>Number of patients experiencing benefit (%)</th>
<th>Average beneficial change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak Pressure</td>
<td>Reduced Pressure</td>
<td>50</td>
<td>1</td>
</tr>
<tr>
<td>Peak Pressure at Metatarsals</td>
<td>Reduced Pressure</td>
<td>53</td>
<td>11</td>
</tr>
<tr>
<td>Peak Pressure at Heel</td>
<td>Reduced Pressure</td>
<td>50</td>
<td>2</td>
</tr>
<tr>
<td>Total Contact Area of Foot</td>
<td>Increased Contact Area</td>
<td>53</td>
<td>1</td>
</tr>
<tr>
<td>Total Contact Area of Metatarsals</td>
<td>Reduced Contact Area</td>
<td>63</td>
<td>17</td>
</tr>
<tr>
<td>Total Contact Area at Heel and Arch</td>
<td>Increased Contact Area</td>
<td>67</td>
<td>10</td>
</tr>
<tr>
<td>Y - Coordinate of the Centre of Pressure</td>
<td>Movement of Centre of Pressure Closer to Heel</td>
<td>60</td>
<td>1</td>
</tr>
</tbody>
</table>

As can be seen from the data in Table 2, Insole A reduced the peak pressures applied to the foot of the patient, compared with the comparison insole. In particular, the peak pressure applied to the metatarsal region of the foot was again significantly reduced.
Representative pressure distribution patterns for the static tests for a patient are shown in Figure 6, in particular a patient wearing no insole (Figure 6a), Insole A (Figure 6b), and Comparative A (Figure 6c).

b) Dynamic Tests

The results of the dynamic tests are set out in Tables 3 and 4 below.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Change monitored</th>
<th>Number of patients benefiting (%)</th>
<th>Average beneficial change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre of Pressure Trajectory</td>
<td>Improved Trajectory</td>
<td>92</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td>Trajectory throughout the Gait Cycle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peak Pressure at Metatarsals throughout the Gait Cycle</td>
<td>Reduced Pressure</td>
<td>75</td>
<td>3</td>
</tr>
<tr>
<td>Metatarsal Peak Pressure at Terminal Stance</td>
<td>Reduced Pressure</td>
<td>71</td>
<td>4</td>
</tr>
<tr>
<td>Peak Pressure at Heel throughout Gait Cycle</td>
<td>Reduced Pressure</td>
<td>50</td>
<td>-5</td>
</tr>
<tr>
<td>Contact Area at the Metatarsals throughout the Gait Cycle</td>
<td>Increased Contact Area</td>
<td>71</td>
<td>6</td>
</tr>
<tr>
<td>Area Description</td>
<td>Contact Area</td>
<td>Speed</td>
<td>Area Description</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
<td>--------------</td>
<td>-------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Contact Area at Metatarsals at Toe-Off</td>
<td>Increased Contact Area</td>
<td>63</td>
<td>Increased Contact Area at Heel at Heel Strike</td>
</tr>
<tr>
<td>Contact Area at Heel at Heel Strike</td>
<td>Increased Contact Area</td>
<td>58</td>
<td>Total Contact Area throughout the Gait Cycle</td>
</tr>
<tr>
<td>Total Contact Area over the Foot at Heel Strike</td>
<td>Increased Contact Area</td>
<td>63</td>
<td>Total Contact Area over the Foot at Mid-Stance</td>
</tr>
<tr>
<td>Total Contact Area over the Foot at Terminal Stance</td>
<td>Increased Contact Area</td>
<td>88</td>
<td>Total Contact Area over the Foot at Toe-Off</td>
</tr>
<tr>
<td>Velocity of the Foot at Toe-Off</td>
<td>Increased Speed</td>
<td>79</td>
<td></td>
</tr>
</tbody>
</table>

As can be seen from the data in Table 3, Insole A improved the centre of pressure trajectory over the foot of the patient. This is a result of the posting material in the insole. Further, Insole A significantly reduces the key peak pressures on the foot of the patient.
Table 4: Comparison between Insoles A and Comparison A

<table>
<thead>
<tr>
<th>Variable</th>
<th>Change monitored</th>
<th>Number of monitored patients experiencing beneficial change (%)</th>
<th>Average beneficial change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre of Pressure Trajectory</td>
<td>Improved Trajectory throughout the Gait Cycle</td>
<td>77</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Peak Pressure at Metatarsals throughout the Gait Cycle</td>
<td>Reduced Pressure</td>
<td>62</td>
<td>3</td>
</tr>
<tr>
<td>Metatarsal Peak Pressure at Terminal Stance</td>
<td>Reduced Pressure</td>
<td>62</td>
<td>3</td>
</tr>
<tr>
<td>Peak Pressure at Heel throughout Gait Cycle</td>
<td>Reduced Pressure</td>
<td>54</td>
<td>2</td>
</tr>
<tr>
<td>Contact Area at the Metatarsals throughout the Gait Cycle</td>
<td>Increased Contact Area</td>
<td>50</td>
<td>1</td>
</tr>
<tr>
<td>Contact Area at Metatarsals at Toe-Off</td>
<td>Increased Contact Area</td>
<td>46</td>
<td>1</td>
</tr>
<tr>
<td>Contact Area at Heel at Heel Strike</td>
<td>Increased Contact Area</td>
<td>46</td>
<td>2</td>
</tr>
<tr>
<td>Total Contact Area throughout the Gait Cycle</td>
<td>Increased Contact Area</td>
<td>50</td>
<td>0</td>
</tr>
<tr>
<td>Total Contact Area</td>
<td>Increased Contact</td>
<td>46</td>
<td>-2</td>
</tr>
</tbody>
</table>
As can be seen from the data in Table 3, Insole A reduced the peak pressures applied to the foot of the patient, compared with the comparison insole. In particular, the peak pressure applied to the metatarsal region of the foot was again significantly reduced. The loading times on the heel and metatarsals of the foot of the user were also significantly reduced using Insole A.

Representative pressure distribution patterns for the dynamic tests for a patient wearing Insole A, Comparative A, and without wearing an insole are shown in Figure 7.
CLAIMS

1. An orthopaedic insole for an item of footwear for a diabetic user, the insole comprising:
   a heel portion for underlying the heel of the foot of the user; and
   a mid portion for underlying the longitudinal arch of the foot of the user;
   wherein the thickness of the mid portion across the width of the longitudinal arch of the foot of the user is greater than the thickness of the heel portion.

2. The insole according to claim 1, wherein the ratio of the thickness of the mid-portion to the thickness of the heel portion is at least 1.5.

3. The insole according to claim 2, wherein the ratio is at least 2.0.

4. The insole according to any preceding claim, wherein the mid-portion has a thickness of up to 25.0 mm.

5. The insole according to claim 4, wherein the mid-portion has a thickness of up to 20.0 mm.

6. The insole according to any preceding claim, wherein the medial region of the mid-portion is thicker than the lateral region of the mid-portion.

7. The insole according to claim 6, wherein the ratio of the thickness of the medial portion to the lateral portion is up to 2.5.

8. The insole according to any preceding claim, wherein the heel portion is provided with a heel cup for accommodating the heel of the foot of the user.

9. The insole according to any preceding claim, wherein the insole further comprises a fore-foot portion.
10. The insole according to claim 9, wherein the ratio of the thickness of the mid-portion to the thickness of the fore-foot portion is at least 1.5.

11. The insole according to either of claims 9 or 10, wherein the fore-foot portion has a thickness of at least 3.0 mm.

12. The insole according to any of claims 9 to 11, wherein the thickness of the lateral region of the fore-foot portion is greater than the thickness of the medial region.

13. The insole according to claim 12, wherein the ratio of the thickness of the lateral region to the medial region is at least 1.5.

14. The insole according to any preceding claim, wherein the insole is formed from a high density foam.

15. The insole according to claim 14, wherein the high density foam is a polyurethane.

16. The insole according to any preceding claim, wherein the insole is formed from a single piece of posting material.

17. The insole according to any preceding claim, wherein the insole comprises a plurality of layers of posting material.

18. The insole according to any preceding claim, further comprising a layer of shock-absorbing material.

19. The insole according to claim 18, wherein the shock-absorbing material is a polyurethane foam.

20. The insole according to any preceding claim, further comprising a layer of memory material.
21. The insole according to claim 20, wherein the layer of memory material overlies the entire insole.

22. An insole for an item of footwear, the insole comprising an upper surface having a mid-portion underlying the longitudinal arch of the foot of a user, the mid-portion having a medial region, the medial region of the mid-portion of the upper surface having a first coefficient of friction, the remaining regions of the upper surface of the insole having a second coefficient of friction, the first coefficient of friction being greater than the second coefficient of friction.

23. The insole according to claim 22, wherein the medial region extends in the lateral direction to at least the centre of the mid-portion.

24. The insole according to claim 23, wherein the medial region extends in the lateral direction two thirds of the width of the mid-portion.

25. The insole according to any of claims 22 to 24, wherein the first coefficient of friction is greater than 1.0.

26. The insole according to claim 25, wherein the first coefficient of friction is greater than 2.0.

27. The insole according to any of claims 22 to 26, wherein the second coefficient of friction is less than 1.0.

28. The insole according to claim 27, wherein the second coefficient of friction is less than 0.8.

29. The insole according to claim 28, wherein the second coefficient of friction is less than 0.5.

30. The insole according to any of claims 22 to 29, wherein the medial region of the surface is provided by a layer of high friction material.
31. The insole according to claim 30, wherein the high friction material is a natural or synthetic rubber.

32. The insole according to any of claims 22 to 31, wherein the remaining regions of the surface of the insole are provided by a layer of low friction material.

33. The insole according to claim 32, wherein the low friction material is a natural or synthetic leather or pigskin.

34. The insole according to any of claims 22 to 33, wherein the upper surface of the insole is provided with anti-microbial properties.

35. An item of footwear comprising an insole according to any preceding claim.

36. A method of adjusting the gait of a subject comprising providing in an item of footwear being worn by the subject an insole according to any of claims 1 to 34.

37. The method according to claim 36, wherein the subject is diabetic.
<table>
<thead>
<tr>
<th>Stage in the gait cycle:</th>
<th>Toe-Off</th>
<th>Mid-Stance</th>
<th>Heel Strike</th>
<th>Global pressures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insoles worn:</td>
<td>No insoles:</td>
<td>DDFO:</td>
<td>Standard:</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 2**