US 20200029653A1

(19) United States
(12) Patent Application Publication
YANG et al.
(10) Pub. No.: US 2020/0029653 A1
(43) Pub. Date: Jan. 30, 2020

(54) INSOLE FOR RELIEVING PLANTAR FACSIITIS PAIN

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(21) Appl. No.: **16/603,538**

(22) PCT Filed: **Dec. 7, 2017**

(86) PCT No.: **PCT/US2017/064994**

§ 371 (c)(1),
(2) Date: **Oct. 7, 2019**

Related U.S. Application Data

(60) Provisional application No. 62/483,135, filed on Apr. 7, 2017.

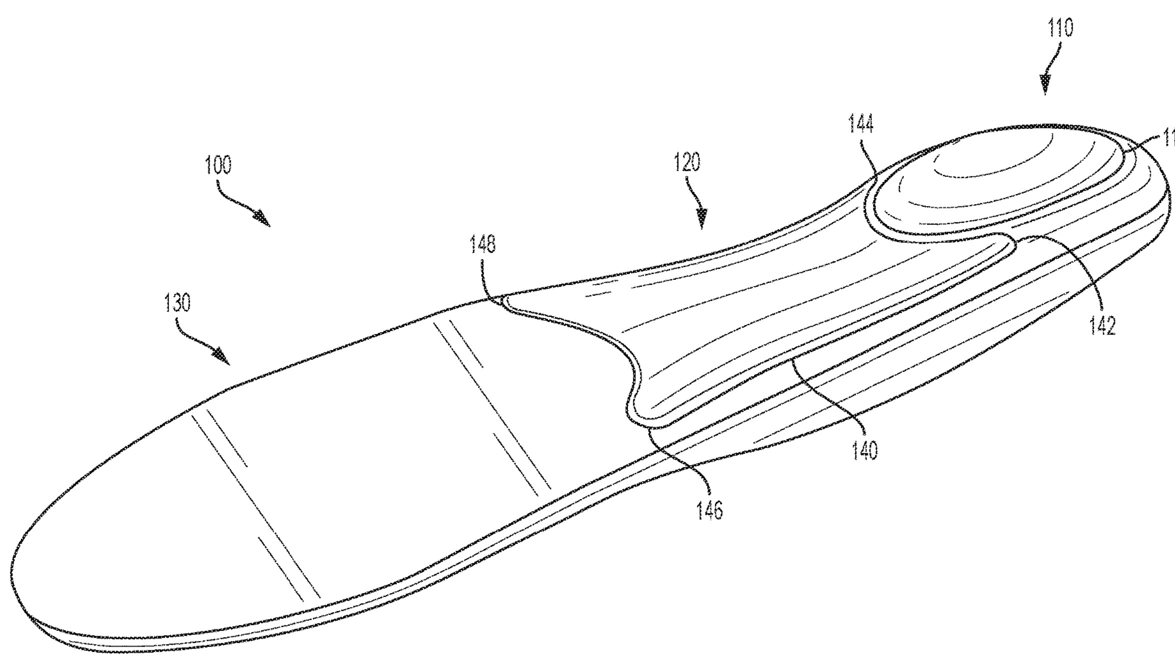
Publication Classification

(51) **Int. Cl.**
A43B 17/00 (2006.01)

(52) **U.S. Cl.**
CPC ***A43B 17/003*** (2013.01)

(57) **ABSTRACT**

An insole for insertion into footwear, including a base layer extending through a forefoot portion, a midfoot portion, and a heel portion of the insole, and an arch shell in the midfoot portion of the insole beneath the base layer, wherein the arch shell has a thickness of no more than 2 mm.



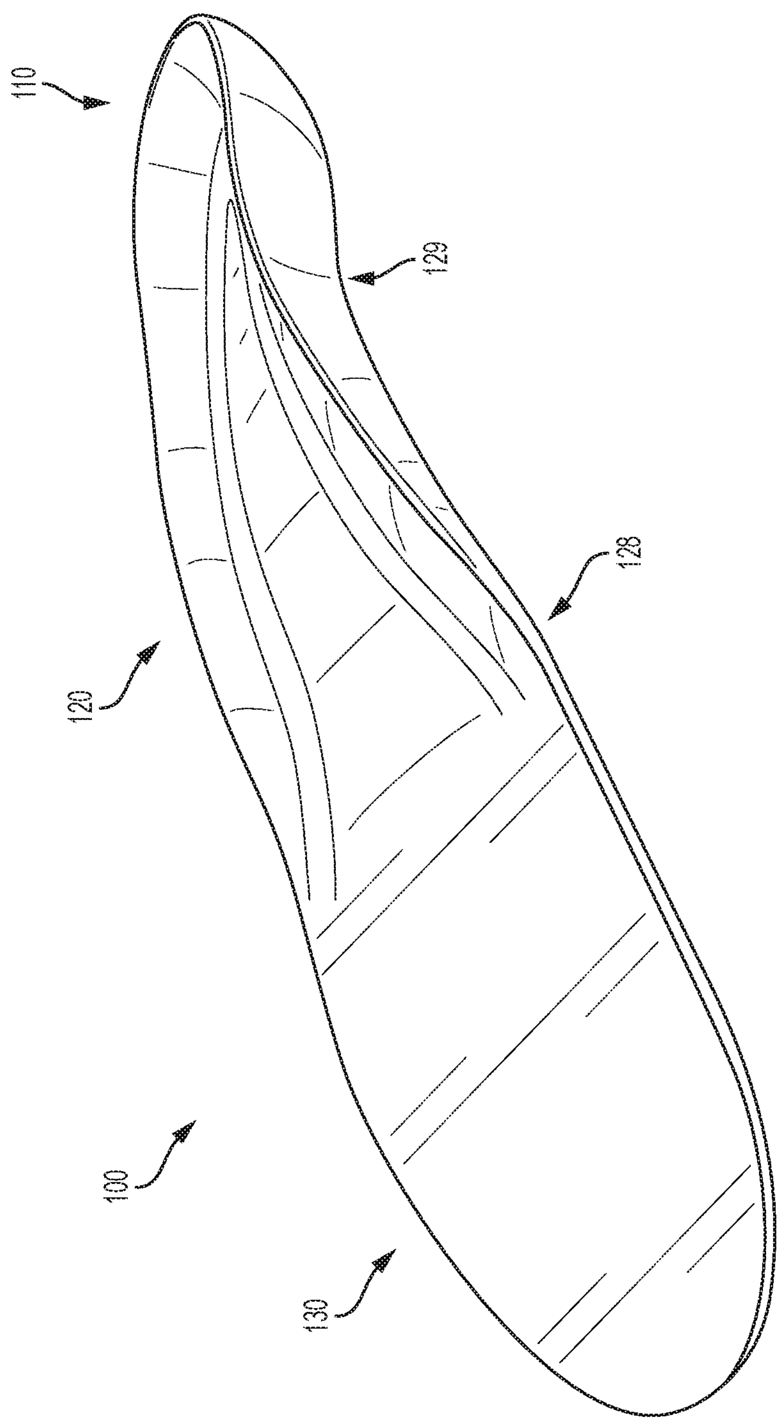


FIG. 1

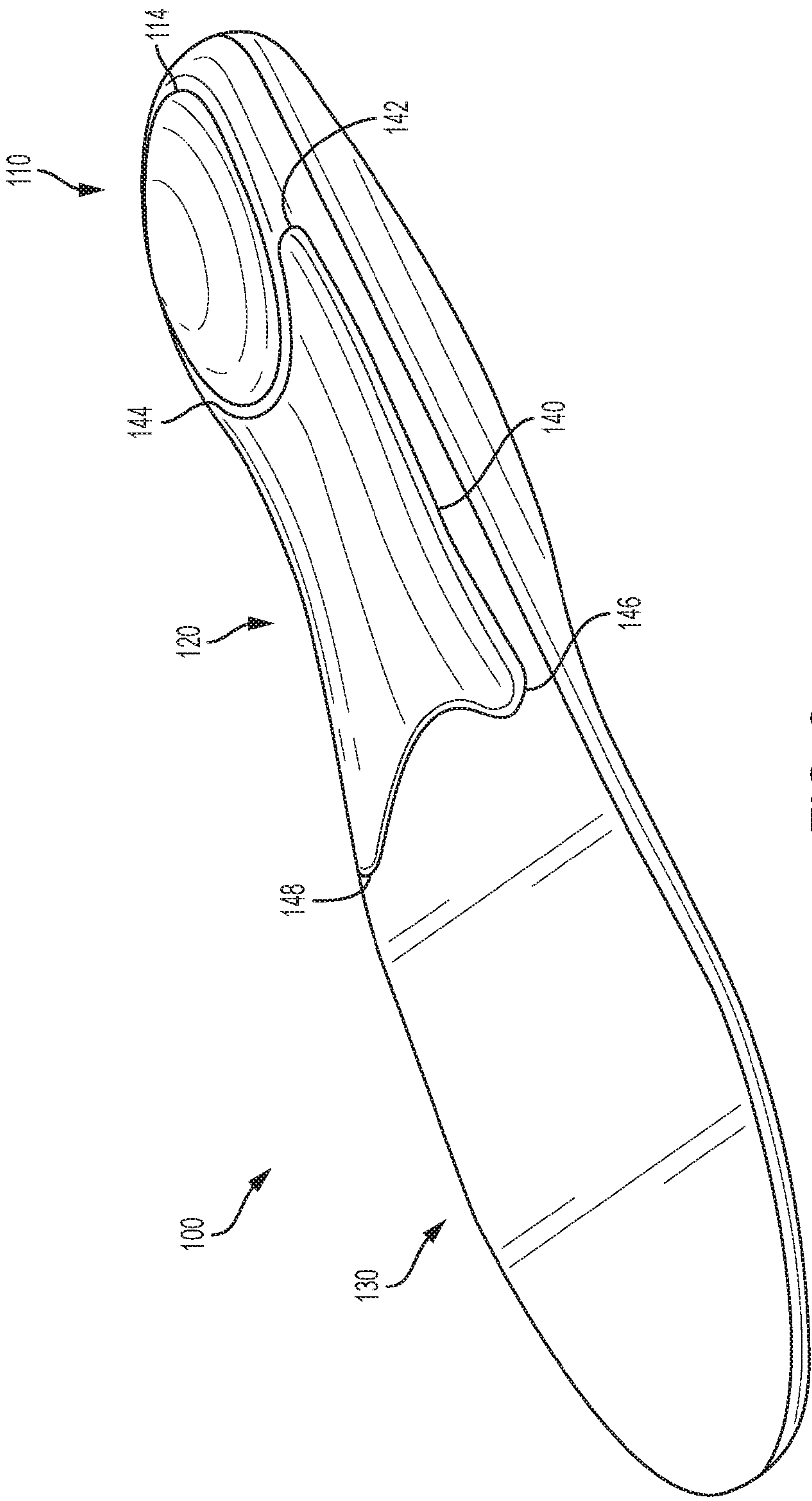


FIG. 2

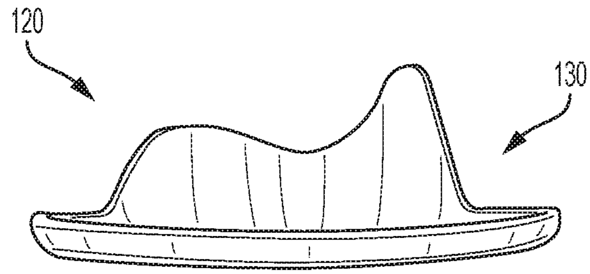


FIG. 3

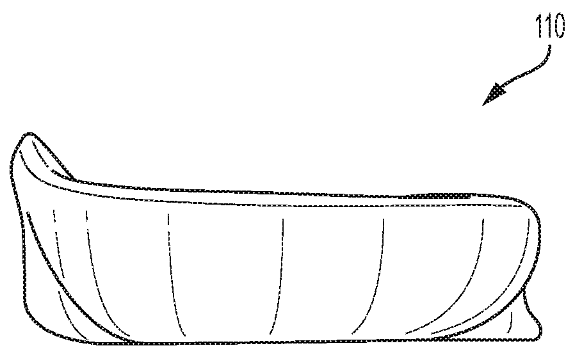


FIG. 4

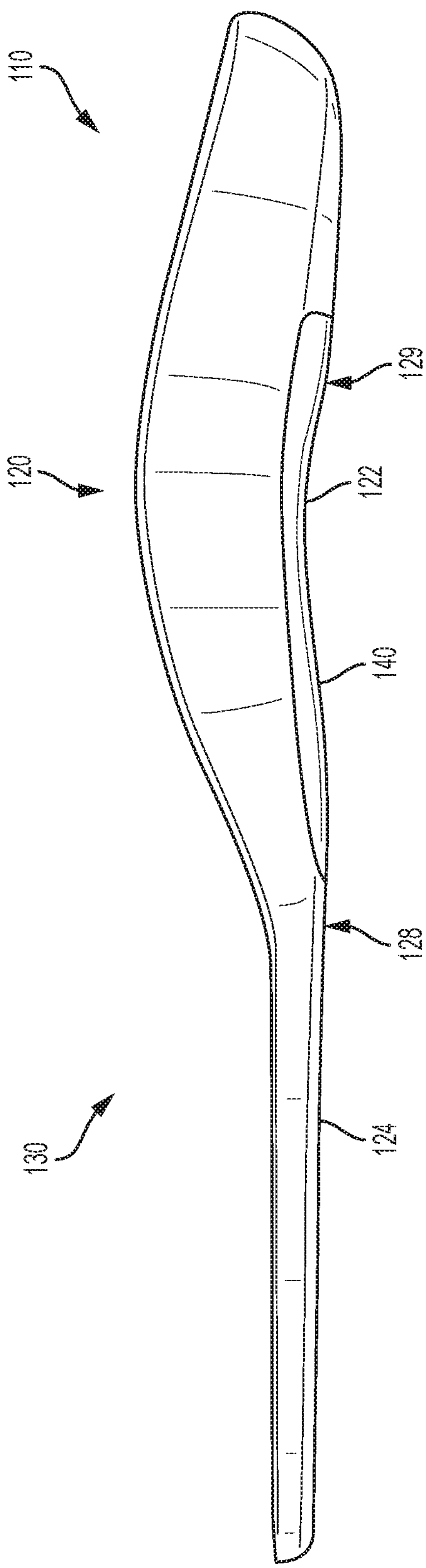


FIG. 5

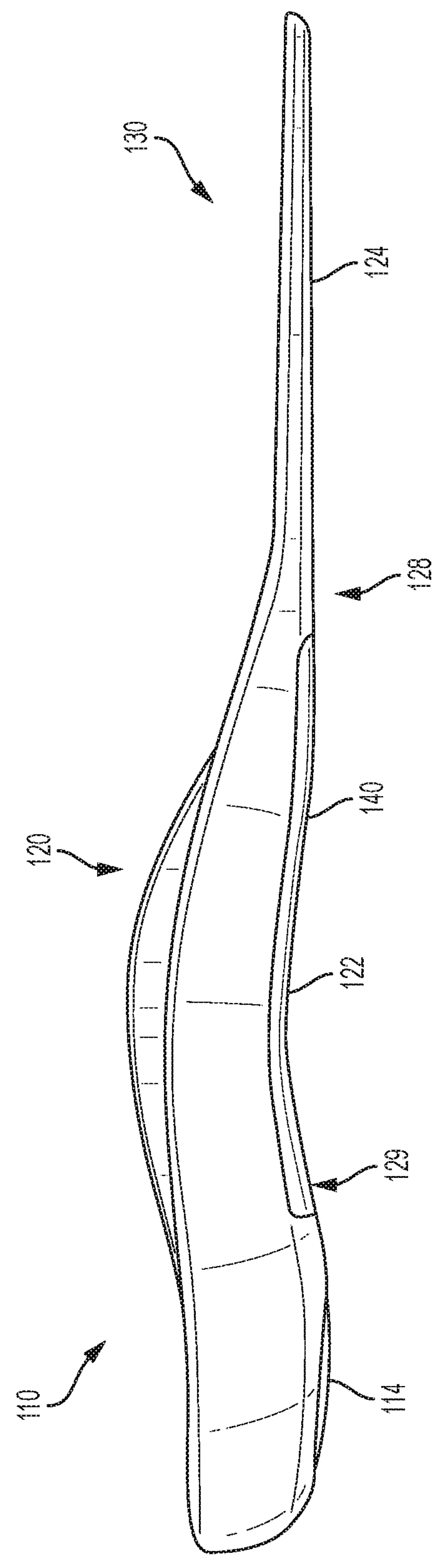


FIG. 6

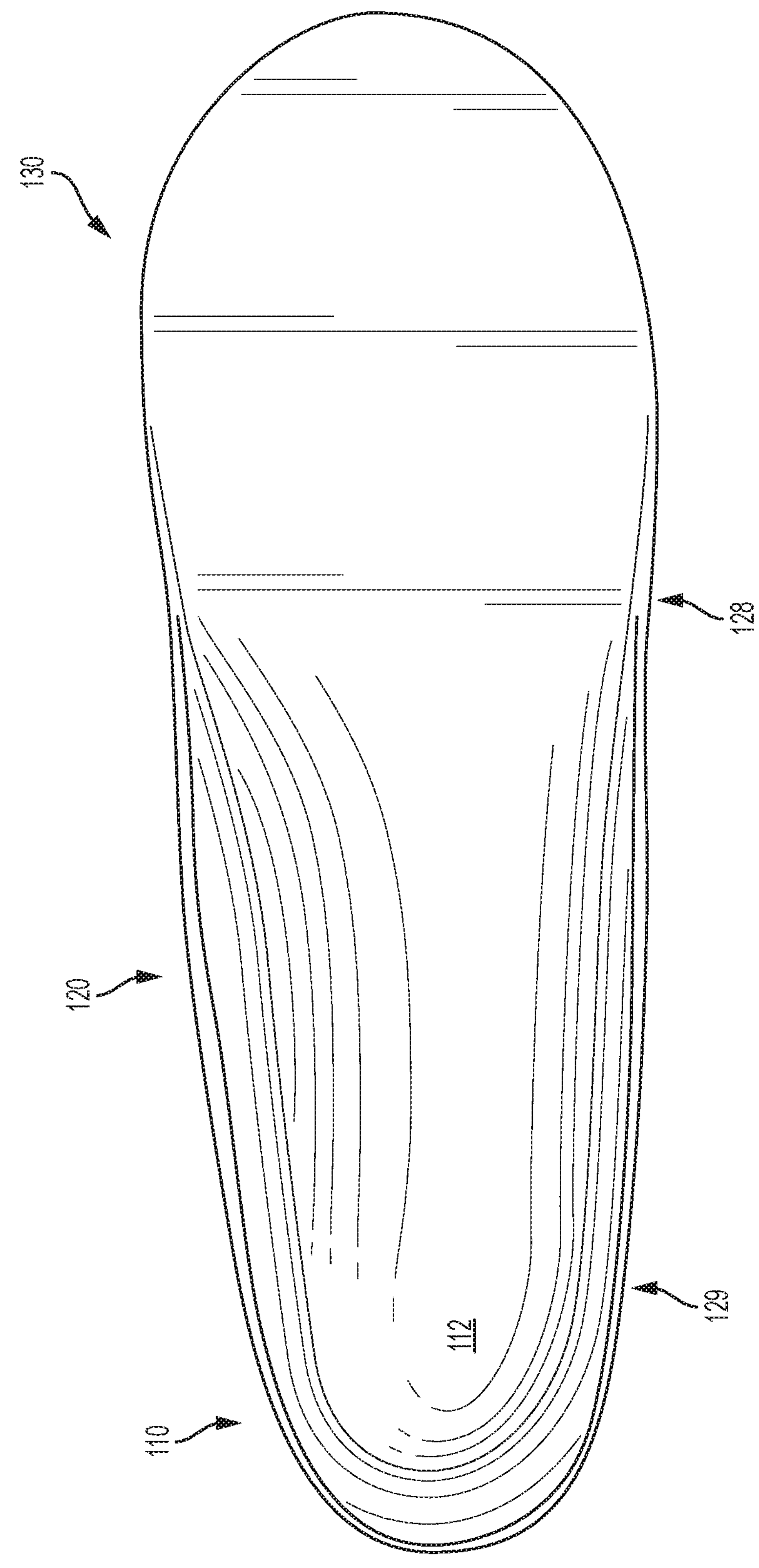


FIG. 7

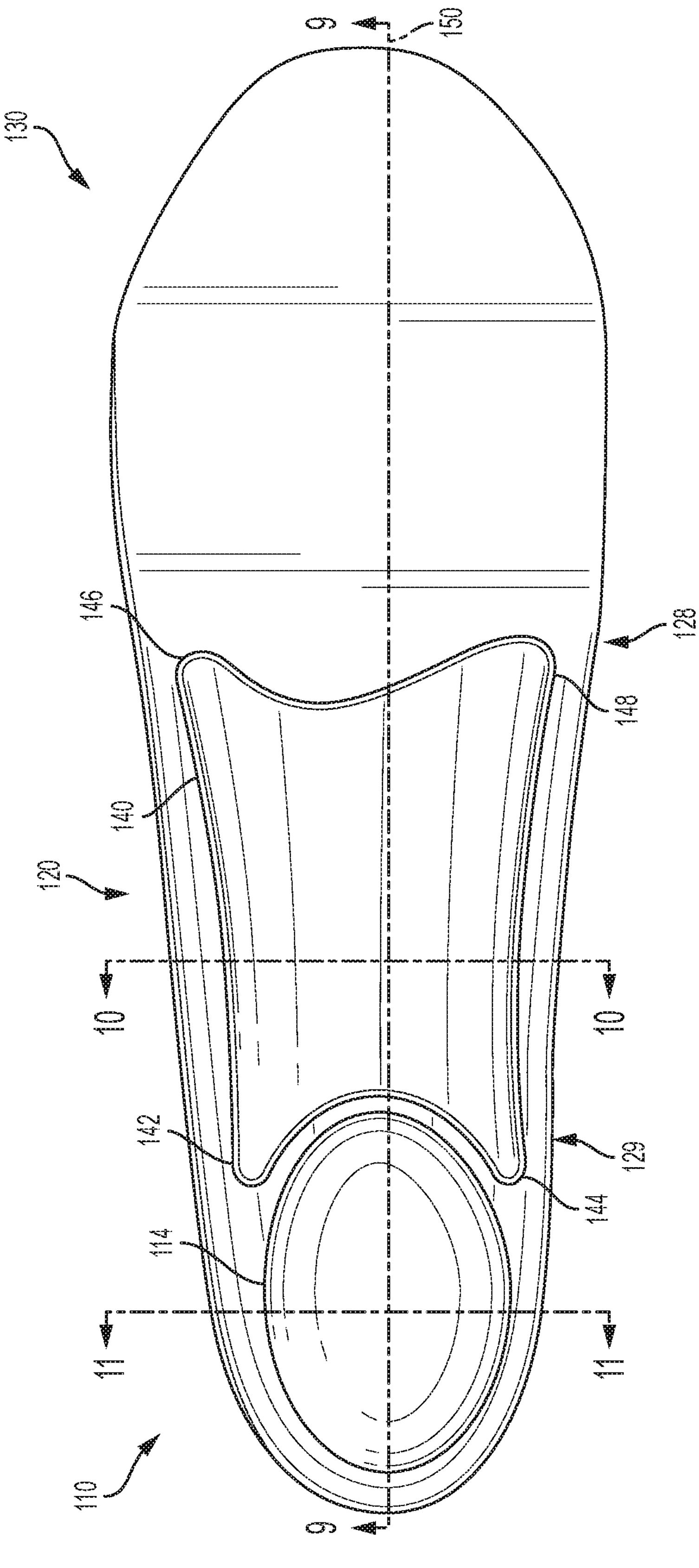


FIG. 8

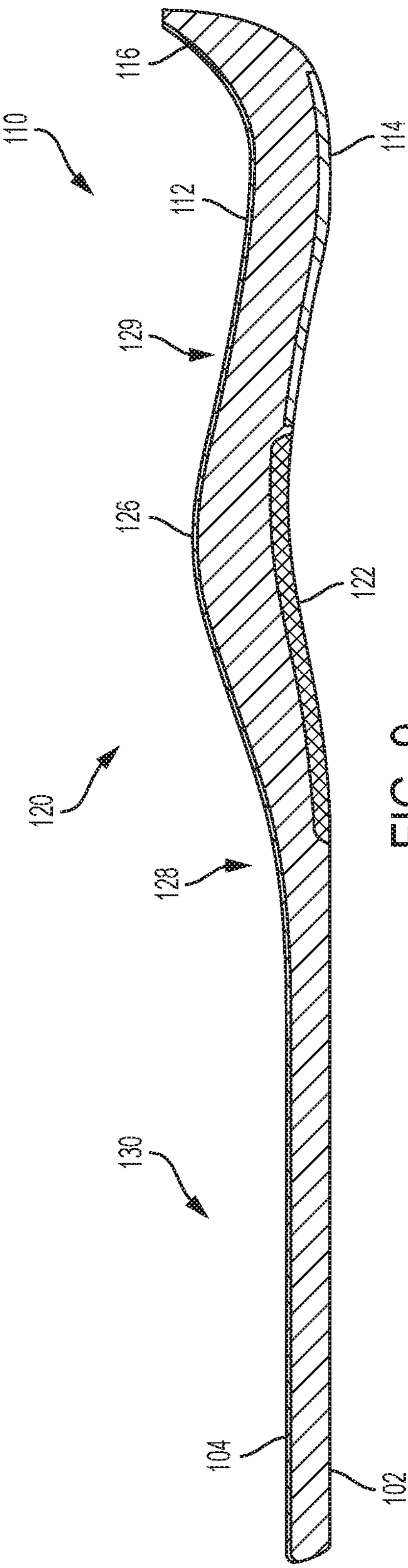


FIG. 9

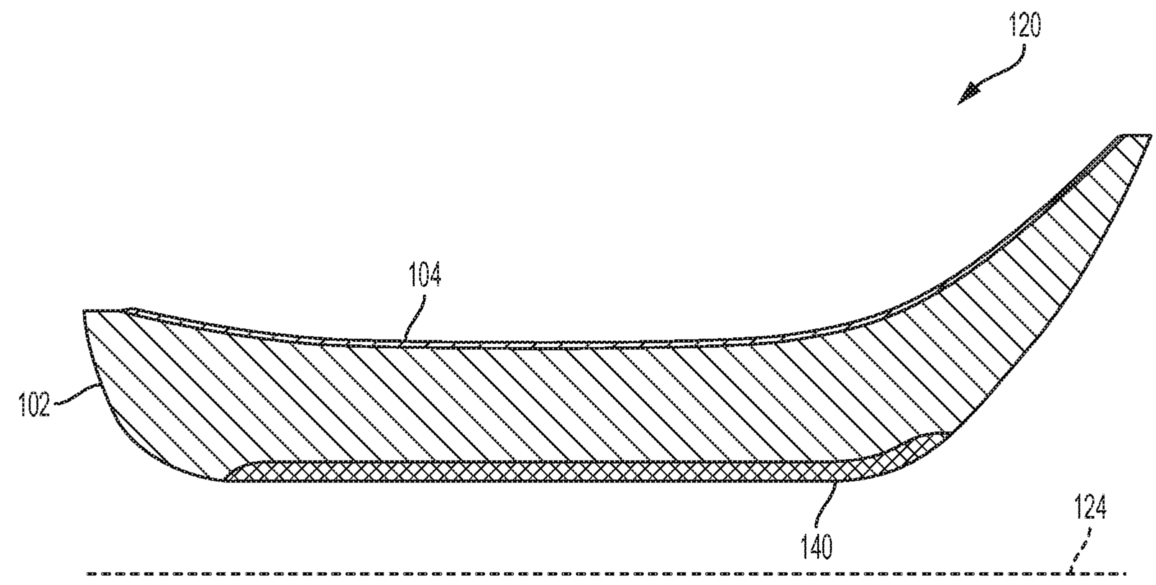


FIG. 10

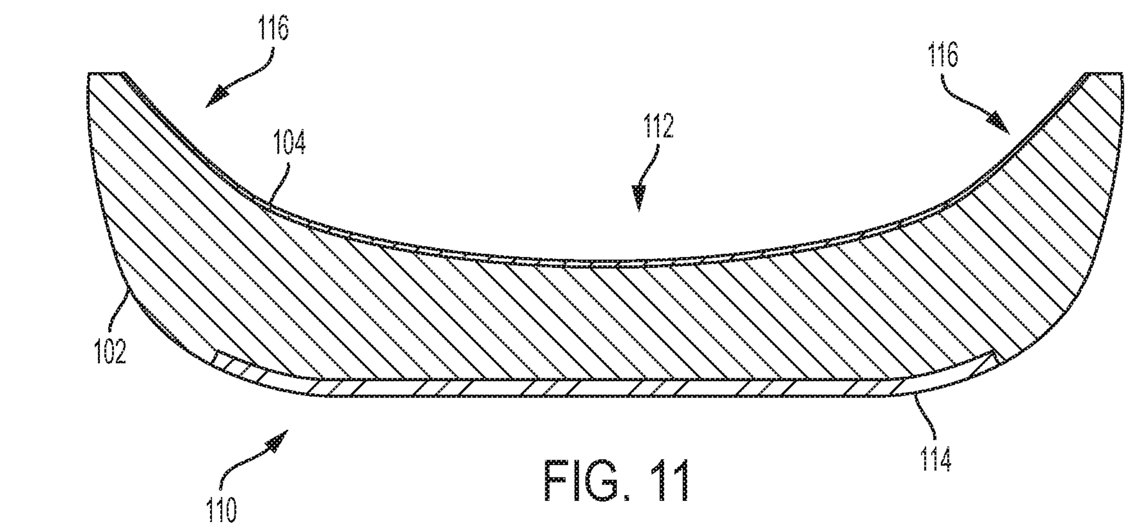


FIG. 11

INSOLE FOR RELIEVING PLANTAR FACSIITIS PAIN

FIELD OF THE INVENTION

[0001] This invention relates generally to insoles for footwear and, more specifically, to insoles for relieving pain.

BACKGROUND OF THE INVENTION

[0002] Plantar fasciitis is a common condition that is related to overuse and aggravation of the plantar fascia. The plantar fascia is a thick layer of tissue that runs along the majority of the bottom side of a human's foot, connecting the heel and metatarsals. The plantar fascia and underlying hallucis longus tendon supports the arch of the foot supports the big toe, which in turn, enables walking and running. When the plantar fascia becomes strained, the arch can weaken, flatten, and become swollen and inflamed. This condition displaces and causes damage to the soft fatty pad under the heel, causing extreme pain, which can limit one's ability to stand or walk.

[0003] Conventionally, contoured insoles have arch portions that support the arch of the foot to reduce arch flattening as a wearer stands and moves. The arch portions are often made primarily of thick, bulky insole material, such as a foam material. This can be disadvantageous, for example, when used with shoes having a built-in arch portion, since the thick, bulky arch portion introduces excessive bulk under the foot that can cause foot discomfort.

SUMMARY OF THE INVENTION

[0004] According to some embodiments, an insole for alleviating pain associated with plantar fasciitis includes an arch portion that provides a balance between stiffness and cushioning specifically configured to relieve plantar fasciitis pain. The insole includes a contoured base layer that extends the length and width of the insole. A thin, contoured arch shell formed from a stiffer material than the material of the base layer is provided on the bottom of the arch portion of the insole. The stiffness, thinness, and contouring of the arch shell in combination with the cushioning of the base layer provides a balance between stiffness and cushioning that was unexpectedly discovered to be ideal for alleviating plantar fasciitis pain.

[0005] According to some embodiments, an insole for insertion into footwear includes a base layer extending through a forefoot portion, a midfoot portion, and a heel portion of the insole, and an arch shell in the midfoot portion of the insole beneath the base layer, wherein the arch shell has a thickness of no more than 2 mm.

[0006] In any of these embodiments, the midfoot portion of the insole may include a flexural stiffness of 25 pounds per inch or less. In any of these embodiments, the midfoot portion of the insole may include a flexural stiffness of 8 pounds per inch or more.

[0007] In any of these embodiments, the insole may be configured such that the forefoot portion of the insole extends at least to distal ends of metatarsals of a foot. In any of these embodiments, the heel portion may be a cupped heel portion. In any of these embodiments, in the midfoot portion, the base layer may include an upwardly extending contour for supporting a foot arch.

[0008] In any of these embodiments, the forefoot portion may have at least a first thickness and the midfoot portion may have at least a second thickness that is greater than the first thickness. In any of these embodiments, the base layer may include a material having a first hardness and the arch shell may include a material having a second hardness that is greater than the first hardness.

[0009] In any of these embodiments, the arch shell may have a constant thickness. In any of these embodiments, the insole may include a heel insert in the heel portion. In any of these embodiments, the arch shell may include at least one extension located at least partially along the heel portion rearward of the forewardmost portion of the heel insert. In any of these embodiments, the insole may include a cover layer on at least a portion of an upper surface of the base layer. In any of these embodiments, the insole may be a removable insole for insertion into footwear.

[0010] According to some embodiments, an insole for insertion into footwear includes a base layer extending through a forefoot portion, a midfoot portion, and a heel portion of the insole, and an arch shell in the midfoot portion of the insole beneath the base layer, wherein the midfoot portion of the insole comprises a flexural stiffness of 25 pounds per inch or less.

[0011] In any of these embodiments, the midfoot portion may include a flexural stiffness of 8 pounds per inch or more. In any of these embodiments, the insole may be configured such that the forefoot portion extends at least to distal ends of metatarsals of a foot. In any of these embodiments, the heel portion may be a cupped heel portion.

[0012] In any of these embodiments, in the midfoot portion, the base layer may include an upwardly extending contour for supporting a foot arch. In any of these embodiments, the forefoot portion may have at least a first thickness and the midfoot portion has at least a second thickness that is greater than the first thickness.

[0013] In any of these embodiments, the base layer may include a material having a first hardness and the arch shell may include a material having a second hardness that is greater than the first hardness. In any of these embodiments, the arch shell may have a constant thickness. In any of these embodiments, the insole may include a heel insert in the heel portion.

[0014] In any of these embodiments, the arch shell may include at least one extension located at least partially along the heel portion rearward of the foreward most portion of the heel insert. In any of these embodiments, the insole may include a cover layer on at least a portion of an upper surface of the base layer. In any of these embodiments, the insole may be a removable insole for insertion into footwear.

[0015] According to some embodiments, a set of removable insoles includes at least one removable insole that includes a base layer extending through a forefoot portion, a midfoot portion, and a heel portion of the insole and an arch shell in the midfoot portion of the insole beneath the base layer, wherein the arch shell has a thickness of no more than 2 mm.

[0016] In any of these embodiments, the set includes instructions for using the set of removable insoles for relieving plantar fasciitis pain.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

[0018] FIG. **1** shows a top perspective view of a right foot insole according to an embodiment;

[0019] FIG. **2** shows a bottom perspective view of the insole of FIG. **1**;

[0020] FIG. **3** is a front view of the insole of FIG. **1**;

[0021] FIG. **4** is a rear view of the insole of FIG. **1**;

[0022] FIG. **5** is a left side view of the insole of FIG. **1**;

[0023] FIG. **6** is a right side view of the insole of FIG. **1**;

[0024] FIG. **7** is a top view of the insole of FIG. **1**;

[0025] FIG. **8** is a bottom view of the insole of FIG. **1**;

[0026] FIG. **9** is a cross-sectional view of the insole of FIG. **1**, taken along line **9-9** of FIG. **8**;

[0027] FIG. **10** is a cross-sectional view of the insole of FIG. **1**, taken along line **10-10** of FIG. **8**; and

[0028] FIG. **11** is a cross-sectional view of the insole of FIG. **1**, taken along line **11-11** of FIG. **8**;

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0029] Described herein are insoles for insertion into footwear. According to some embodiments, insoles are configured to provide cushioning and support tailored to wearers that are experiencing plantar fasciitis pain. The insoles are configured with a base cushioning layer and an arch shell of stiffer material along the midfoot area—the area extending beneath the wearer's arch. The inventors of the present invention unexpectedly discovered that a thin arch shell, in accordance with the features described below, provides enough support to alleviate pain associated with plantar fasciitis without having the stiffness that can increase plantar fasciitis pain.

[0030] Plantar fasciitis can be associated with weakening of the arch, so insoles with good arch support are desirable for sufferers of plantar fasciitis pain. However, insoles with good arch support are often bulky and difficult to fit into shoes, especially shoes with existing arch supports. Conventional insoles with thinner arches include a layer of stiffer material along the arch, which provides arch support without as much of the bulk, making these thinner insoles easier to insert into footwear. The inventors of the present invention discovered, however, that existing thinner insoles, while providing comfort to normal wearers, can aggravate the plantar fascia of wearers with plantar fasciitis, causing discomfort and pain. Described herein are insoles having a significantly thinner layer of stiff material along the arch than conventional insoles. The thinness, material, and shape of the layer of stiff material in combination with a base layer of more compliant material, reduces the arch flattening associated with plantar fasciitis without being overly rigid and without causing the irritation to the inflamed plantar fascia associated with known thinner insoles.

[0031] An insole, according to the principles described herein, includes a contoured arch that provides the ideal amount of stiffness for the arches of sufferers of plantar fasciitis. The insole includes a base layer of cushioning material that extends the length and width of the insole. An arch shell is provided along the underside of the base layer in the midfoot portion of the insole. The curvature of the arch shell provides structure and stiffness to the arch support of the insole.

[0032] Thus, a low profile insole is provided that has the ideal balance between arch support and flexibility for wearer's experience plantar fasciitis pain. The arch stiffness of the insole is high enough to reduce the arch flattening associated with plantar fasciitis while being low enough to not provide an overly stiff arch that would irritate the plantar fascia and cause pain. The thinness of the arch shell provided a surprising benefit to wearers with plantar fasciitis. It was thought that a shell of such thinness would have little or no effect on easing plantar fasciitis pain relative to an insole of similar overall thickness but lacking the shell. However, it was discovered that the arch shell, layered with the base layer, provided just enough arch support that pain associated with plantar fasciitis reduce significantly. Because of its low profile, the insole can be inserted into any footwear (even footwear with built-in arch supports) without introducing excessive bulk under the foot that can cause discomfort, even for wearers without plantar fasciitis.

[0033] FIGS. **1-11** illustrate a right-foot insole **100** according to some embodiments. Insole **100** is configured to be placed in an article of footwear to provide cushioning and support for alleviating problems associated with plantar fasciitis. Although the figures and following description describe a right-foot insole, it is to be understood that the left-foot insole is generally a mirror image of the right-foot insole, and thus, the features described below pertain to a left-foot insole as well.

[0034] Insole **100** includes heel portion **110**, midfoot portion **120**, and a forefoot portion **130**. As illustrated in the top and bottom views of FIGS. **7** and **8**, the perimeter of insole **100** is generally shaped to follow the outline of a typical wearer's foot. Moving from back to front along the insole **100**, the forefoot portion **130** broadens slightly to a maximum width that is configured to be located generally beneath the broadest portion of a wearer's foot, i.e., beneath the distal heads of the metatarsals. Forefoot portion **130** then narrows into a curved end that may be shaped to follow the general outline of the toes of a typical wearer's foot. Moving rearward from forefoot portion **130**, the midfoot portion **120** and heel portion **110** narrow slightly to a curved end configured to follow the outline of a typical wearer's heel.

[0035] As illustrated in the side views of FIGS. **5** and **6**, the forefoot portion **130** is generally flat. In some embodiments, the forefoot portion **130** has a uniform thickness. In other embodiments, forefoot portion **130** may include a nonuniform thickness with one or more areas of increased thickness, for example, located to provide additional support at areas of maximum pressure on a wearer's forefoot. For example, an area of increased thickness may be provided at an area of the forefoot portion **130** located proximal to the wearer's second and third metatarsals, which is typically the location of the greatest pressure in the forefoot during the "toe off" phase of a step.

[0036] Forward to rearward, the upper surface of the midfoot portion **120** is contoured to follow the shape of a wearer's arch. In some embodiments, this contour is achieved, at least in part, by an upward arching of the entire midfoot portion such that the bottom surface **122** of the midfoot portion **120** arches upward relative to a plane coincident with the bottom planar surface **124** of the forefoot portion **130**. In other embodiments, the contour may be achieved by an increase in thickness of the midfoot portion **120** or by a combination of an increase in thickness and an upward arching of the midfoot portion **120**. For example, as shown in FIG. **9**, the maximum height **126** of midfoot portion **120** along the midline **150** of the insole **100** is achieved by a combination of an overall arching of the midfoot portion **120** (i.e., the midfoot portion rises above a plane coincident with the bottom surface **124** of the forefoot portion **130** and heel portion **110**) and an increase in thickness of midfoot portion **120** from a minimum at the juncture **128** with the forefoot portion **130**.

[0037] In some embodiments, the cross-sectional thickness of the midfoot portion **120** along the midline **150** of the insole **100** (e.g., the cross-section illustrated in FIG. **9**) is of the same or similar thickness as the forefoot portion **130**. In some embodiments, along the midline, midfoot portion **120** gradually thickens from the forefoot portion **130** to a maximum thickness that is maintained through the remainder of the midfoot portion **120**. In other embodiments, along the midline, the thickness of the midfoot portion **120** reaches a maximum (e.g., at the center point of the arch) and then decreases toward the heel portion **110**. In some embodiment, along the midline, the thickness of the midfoot portion **120** at the juncture **129** with the heel portion **110** is maintained through the heel portion **110**.

[0038] As illustrated in FIG. **10**, which is a cross-sectional view of the midfoot portion **120** through section line **10-10** of FIG. **8**, the midfoot portion **120** may be contoured across its width such that one or both of the sides of the midfoot portion **120** extend upwardly. The upward extension of the inside **128** (medial side) of the midfoot portion (the portion that underlies the arch of a wearer's foot) is configured to follow the contour of the user's arch. The upward extension of the outside **129** (lateral side) of the midfoot portion can provide additional support to the outside of the wearer's foot. The upward extensions of the inside and outside of the midfoot portion **120** can be achieved by increased thickness, by contouring of the overall midfoot portion **120**, or by a combination of thickness increases and contouring. For example, as shown in FIG. **10**, the upward extensions of both the inside and outside of the midfoot portion **120** are achieved with both thickness changes and contouring.

[0039] Heel portion **110** is generally cup shaped and configured to underlie a typical wearer's heel. As illustrated best in FIGS. **1**, **9**, and **11**, heel portion **110** may include a relatively flat central portion **112** and a sloped side wall **116** that extends around the sides and rear of central portion **112**. Generally, when a heel strikes a surface, the fat pad portion of the heel spreads out. A cupped heel portion thereby stabilizes the heel of the wearer and maintains the heel in heel portion **110**, preventing spreading out of the fat pad portion of the heel and also preventing any side-to-side movement of the heel in heel portion **110**. The thickness of the central portion **112** of heel portion **110** may be uniform. The thickness may be uniform with the thickness of the midfoot portion **120** or may be greater than or less than the thickness of the midfoot portion **120**. In some embodiments, the thickness of the heel portion is nonuniform, for example, with a thicker section located centrally in the heel portion such that the area immediately beneath a wearer's heel provides the most cushioning.

[0040] The bottom surface of insole **100** (the surface that contacts the footwear into which it is inserted), may or may not include texturing. Texturing can be useful to provide greater grip to the footwear, preventing shifting of the insole **100** within the footwear. Texturing can be provided on any of the forefoot portion **130**, the midfoot portion **120**, and the heel portion **110**. In some embodiments, the forefoot portion **130** includes one or more pattern trim lines for indicating where to trim the insole **100** to fit into smaller size footwear.

[0041] As illustrated in FIG. **9**, insole **100** includes base layer **102**, which extends the entire length of insole **100**. In some embodiments, cover layer **104** is secured to the upper surface of base layer **102** along the entire length of insole **100**. Cover layer **104** may be secured by any suitable means, such as adhesive, radio frequency welding, etc.

[0042] Base layer **102** can be made from any suitable material including, but not limited to, any flexible material that can cushion and absorb the shock from heel strike on the insole. Suitable shock absorbing materials can include any suitable foam, such as, but not limited to, cross-linked polyethylene, poly(ethylene-vinyl acetate), polyvinyl chloride, synthetic and natural latex rubbers, neoprene, block polymer elastomers of the acrylonitrile-butadiene-styrene or styrene-butadiene-styrene type, thermoplastic elastomers, ethylenepropylene rubbers, silicone elastomers, polystyrene, polyuria, or polyurethane; preferably a flexible polyurethane foam made from a polyol chain and an isocyanate such as a monomeric or prepolymerized diisocyanate based on 4,4'-diphenylmethane diisocyanate (MDI) or toluene diisocyanate (TDI). Such foams can be blown with fluorocarbons, water, methylene chloride or other gas producing agents, as well as by mechanically frothing to prepare the shock absorbing resilient layer. Such foams advantageously can be molded into the desired shape or geometry. Preferably, base layer **102** is made from block copolymer styrene-ethylene-butylene-styrene (SEBS) or from a combination of SEBS and ethylene-vinyl-acetate (EVA). In some embodiments, base layer **102** is formed from 4012-55N and/or 4011-55N SEBS, manufactured by TSRC Corporation of Taiwan. Preferably, base layer **102** is made from a combination of 4012-55N SEBS, 4011-55N SEBS and EVA.

[0043] Non-foam elastomers such as the class of materials known as viscoelastic polymers, or silicone gels, which show high levels of damping when tested by dynamic mechanical analysis performed in the range of −50 degrees C. to 100 degrees C. may also be advantageously employed. Resilient polyurethane can be prepared from diisocyanate prepolymer, polyol, catalyst and stabilizers that provide a waterblown polyurethane foam of the desired physical attributes. Suitable diisocyanate prepolymer and polyol components include polymeric MDI M-10 (CAS 9016-87-9) and Polymeric MDI MM-103 (CAS 25686-28-6), both available from BASF, Parsippany, N.J. U.S.A.; Pluracol 945 (CAS 9082-00-2) and Pluracol 1003, both available from BASF, Parsippany, N.J. U.S.A.; Multrinol 9200, available from Mobay, Pittsburgh, Pa. U.S.A.; MDI diisocyanate prepolymer XAS 10971.02 and polyol blend XUS 18021.00 available from Dow Chemical Company, Midland, Mich. U.S.A.; and Niax 34-28, available from Union Carbide, Danbury, Conn. U.S.A.

[0044] These urethane systems generally contain a surfactant, a blowing agent, and an ultraviolet stabilizer and/or catalyst package. Suitable catalysts include Dabco 33-LV (CAS 280-57-9, 2526-71-8), Dabco X543 (CAS Trade Secret), Dabco T-12 (CAS 77-58-7), and Dabco TAC (CAS 107-21-1) all obtainable from Air Products Inc., Allentown, Pa. U.S.A.; Fomrez UL-38, a stannous octoate, from the Witco Chemical Co., New York, N.Y. U.S.A. or A-1 (CAS 3033-62-3) available from OSI Corp., Norcross, Ga. U.S.A. Suitable stabilizers include Tinuvin 765 (CAS 41556-26-7), Tinuvin 328 (CAS 25973-55-1), Tinuvin 213 (CAS 104810-48-2), Irganox 1010 (CAS 6683-19-8), Irganox 245 (CAS 36443-68-2), all available from the Ciba Geigy Corporation, Greensboro, N.C. U.S.A., or Givsorb UV-1 (CAS 057834-33-0) and Givsorb UV-2 (CAS 065816-20-8) from Givaudan Corporation, Clifton, N.J. U.S.A. Suitable surfactants include DC-5169 (a mixture), DC190 (CAS68037-64-9), DC197 (CAS69430-39-3), DC-5125 (CAS 68037-62-7) all available from Air Products Corp., Allentown Pa. U.S.A. and L-5302 (CAS trade secret) from Union Carbide, Danbury Conn. U.S.A.

[0045] Base layer **102** may be made from a urethane molded material, such as a soft, resilient foam material having Shore Type OO Durometer hardness in the range of 40 to 70, as measured using the test equipment sold for this purpose by Instron Corporation of Canton Mass. U.S.A. Preferably the base layer has a Shore Type OO Durometer hardness in the range of 45 to 55, and more preferably, in the range of 48 to 52. Such materials provide adequate shock absorption for the heel and cushioning for the midfoot and forefoot.

[0046] Alternatively, base layer **102** can be a laminate construction, that is, a multilayered composite of any of the above materials. Multilayered composites are made from one or more of the above materials such as a combination of EVA and polyethylene (two layers), a combination of polyurethane and polyvinyl chloride (two layers), or a combination of ethylene propylene rubber, polyurethane foam, and EVA (3 layers). In some embodiments, base layer **102** is made from a layering of EVA and SEBS.

[0047] Base layer **102** can be prepared by conventional methods, such as heat sealing, ultrasonic sealing, radio-frequency sealing, lamination, thermoforming, reaction injection molding, and compression molding, if necessary, followed by secondary die-cutting or in-mold die cuffing. Representative methods are taught, for example, in U.S. Pat. Nos. 3,489,594; 3,530,489; 4,257,176; 4,185,402; 4,586,273, in Handbook of Plastics, Herber R. Simonds and Carleton Ellis, 1943, New York, N.Y.; Reaction Injection Molding Machinery and Processes, F. Melvin Sweeney, 1987, New York, N.Y.; and Flexible Polyurethane Foams, George Woods, 1982, New Jersey; Preferably, the insole is prepared by a foam reaction molding process such as is taught in U.S. Pat. No. 4,694,589. In some embodiments, base layer **102** is prepared by a conventional direct injection expanded foam molding process. An example of a conventional direct injection molding machine model is KSC908 LE2A, made by King Steel Machinery Co., LTD. of Taiwan.

[0048] Cover layer **104** can be made from any suitable material including, but not limited to, fabrics, leather, leatherboard, expanded vinyl foam, flocked vinyl film, coagulated polyurethane, latex foam on scrim, supported polyurethane foam, laminated polyurethane film or in-mold coatings such as polyurethanes, styrene-butadiene rubber, acrylonitrile-butadiene, acrylonitrile terpolymers and copolymers, vinyls, or other acrylics, as integral top covers. Desirable characteristics of cover layer **104** include good durability, stability and visual appearance. It is also desirable that cover layer **104** has good flexibility, as indicated by a low modulus, in order to be easily moldable. The bonding surface of cover layer **104** should provide an appropriate texture in order to achieve a suitable mechanical bond to the upper surface of base layer **102**. Cover layer **104** can be a fabric, such as a brushed knit laminated top cloth (for example, brushed knit fabric/urethane film/non-woven scrim cloth laminate) or a urethane knit laminate top cloth. Preferably, cover layer **104** is made from a polyester fabric material.

[0049] As illustrated in FIGS. **2**, **8**, **9**, and **11**, heel portion **110** may include an insert **114** that is centrally located in heel portion **110**—the area of heel portion **110** that receives the greatest force from the wearer's heel. Insert **114** can be made of a stiffer material than the material of base layer **102** to provide additional shock absorption without requiring a large increase in thickness of heel portion **110**. Insert **114** may be secured within a shallow recess on the underside of base layer **102**. Insert **114** may be secured by any suitable means, such as adhesive, radio frequency welding, etc. As illustrated in the figures, in some embodiments, insert **114** is oval-shaped, similar to a wearer's heel. Insert **114** can be any shaped, such as circular, rectangular, or irregularly shaped. In some embodiments, heel portion **110** does not include insert **114**.

[0050] Insert **114** may be formed of any suitable material. Suitable synthetic elastomeric polymeric materials comprise for example polymers made from conjugated dienes, for example, isoprene, butadiene, or chlorobutadiene, as well as from co-polymeric materials made from conjugated dienes and vinyl derivatives such as styrene and acrylonitrile. Exemplarily, suitable synthetic rubber materials comprise isoprene rubber, butadiene rubber, chloroprene rubber, styrene butadiene rubber (SBR), nitrilo-butadiene rubber (NBR), also in hydrogenated form, ethylene-propylene-(diene) rubber (EPM, EPBM), ethyl ene vinyl acetate rubber, silicone rubber also including liquid silicone rubber. Preferably, insert **114** is made of poly(styrene-butadiene-styrene) (SBS). According to some embodiments, the insert is a mixture of SBS block copolymer with paraffinic oil. According to some embodiments, insert **114** has a thickness in the range from 0.5 mm to 3 mm, preferably in the range from 0.8 mm to 2 mm, or more preferably in the range from 1 mm to 1.5 mm.

[0051] In some embodiments, forefoot portion **130** may have a thickness in the range of about 1 mm to about 8 mm, preferably in the range of about 2 mm to about 6 mm, more preferably in the range of about 3 mm to about 5 mm. In some embodiments, central portion **112** of heel portion **110** may have a thickness in the range of about 2 mm to about 16 mm, preferably in the range of about 4 mm to about 12 mm, more preferably in the range of about 6 mm to about 10 mm.

[0052] As illustrated in FIGS. **2**, **5**, and **8-10**, midfoot portion **120** of insole **100** includes a flexible and resilient arch shell **140** located in a recess in the underside of base layer **102** in the midfoot portion **120**. Arch shell **140** is made from a stiffer material than that of base layer **102**. Arch shell **140** is contoured in an upwardly arching shape (along the midline **150**), providing the underlying structure of the arch support of insole **100**. The shape, sizing, and material of the arch shell **140**, in combination with the properties of the base layer **102**, is configured to provide: (1) a balance between support and stiffness that was discovered to be ideal for wearers experiencing plantar fasciitis pain, in (2) a non-bulky insole, ideal for fitting into any footwear.

[0053] Typically, arch shell **140** is secured in a recess in base layer **102** by an adhesive, although it could also be placed in a mold, and the base layer **102** can be molded thereon, thereby bonding arch shell **140** to base layer **102** during the molding operation.

[0054] As a person steps on insole **100**, arch shell **140** flattens. During this operation, the flexion changes throughout the step cycle. The edges of arch shell **140** move outwardly so that there is little or no change in resistance to the weight applied to insole **100**. In other words, the resistance remains substantially constant, unlike the bulky foam arch portions of prior art insoles in which resistance increases as a person steps thereon due to the compression of the material. Thus, in the operation of the present invention, arch shell **140** behaves much like the arch of a person's foot, which elongates as it flattens. Accordingly, arch shell **140** follows natural body movements and is more adaptable to the requirements of an individual wearer's foot. Therefore, insole **100**, according to some embodiments, is suitable for different sizes, heights, weights, etc, making it more versatile than conventional insoles having bulky arch portions.

[0055] Arch shell **140** includes rear wing sections **142** and **144** at the rear section that preferably extend slightly into the heel portion **110**. Wing sections **142**, **144** permit natural motion of the foot during a stride, i.e., normal heel to arch progression. Thus, wing sections **142**, **144** allow the arch of the foot to come into play during the latter part of a heel strike, while the wearer's heel is still supported by the full cushion of the heel portion **110**, thereby providing a natural transition. For similar reasons, forward wing sections **146**, **148** may be provided at the forward end of arch shell **140** to provide a natural transition from the midfoot portion **120** to the forefoot portion **130**.

[0056] The geometry and material of the arch support of insole **100** (i.e., midfoot portion **120**) is specifically configured to optimize the stiffness and support for wearers experiencing plantar fasciitis pain. The stiffness and support can be tailored (e.g., for men and women, for adults of different sizes, for children, etc.) by changing the thickness, composition, height of the arch, etc. The stiffness of the arch area of insole **100** is, generally, a function of the material and shape of base layer **102**, the material of arch shell **140**, and the geometry of arch shell **140**.

[0057] Arch shell **140** may be made from thermoplastic material, e.g., thermoplastic polyurethane; foamed materials, e.g. EVA, polyurethane foam; or thermoset materials, e.g., composites. Arch shell **140** may be constructed from a thermoplastic olefin polymer that may be stiff and flexible, e.g., polyethylene, polypropylene, polyurethane, or elastomers, or a combination of thermoplastic polyurethane and acrylonitrile-butadiene-styrene. One example may be UH-64D20 thermoplastic polyurethane (TPU) from Uretech Company, Cheng-Hwa Hsien, Taiwan, Republic of China. Other examples include: a fiberglass filled polypropylene; nylon; fiberglass; polypropylene; woven extrusion composite; ABS; thermoplastic polymer; carbon graphite; polyacetal, for example, that sold under the trademark "DELRIN" by E.I. du Pont de Nemours and Company of Wilmington, Del. U.S.A.; or any other suitable material. Preferably, arch shell **140** is made of TPU, for example, TPU having a Shore hardness of about 95±5 Shore A to about 64±5 Shore D. Generally, the hardness of arch shell **140** is greater than the hardness of base layer **102**. Preferably, arch shell **140** is injection molded.

[0058] The material used for arch shell **140** generally has a flexural modulus in the range of about 25,000 to 125,000 pounds per square inch (1.72×10^8 to 8.63×10^8 Newton/meter^2), preferably in the range of about 35,000 to 100,000 p.s.i. (2.40×10^8 to 6.90×10^8 N/m^2), or more preferably, in the range of about 45,000 to 60,000 p.s.i. (3.10×10^8 to 4.15×10^8 N/m^2). Techniques for measuring flexural modulus are well known to those skilled in the art.

[0059] Arch shell **140** may include a generally constant thickness across its length and/or width (the edges may have a reduced thickness to match a reduced edge depth of the mating recess in base layer **102**). The thickness of the arch shell **140** may range from about 0.5 mm to about 2.5 mm. In some embodiments, the thickness is about 0.7 mm to about 2.0 mm, about 0.8 mm to about 1.5 mm, about 0.9 mm to about 1.1 mm, or, more preferably, about 0.95 mm to about 1.05 mm. The thickness of arch shell **140** may be no more than 2 mm, no more than 1.8 mm, no more than 1.6 mm, no more than 1.5 mm, no more than 1.4 mm, no more than 1.2 mm, no more than 1.1 mm, no more than 1.05 mm, no more than 1 mm, no more than 0.98 mm, no more than 0.95 mm, no more than 0.9 mm, no more than 0.8 mm, or no more than 0.5 mm. The thickness of arch shell **140** may be no less than 0.2 mm, no less than 0.5 mm, no less than 0.7 mm, no less than 0.8 mm, no less than 0.9 mm, no less than 0.95 mm, no less than 1 mm, or no less than 1.2 mm. In some embodiments, the thickness of arch shell **140** is nonuniform. The thickness may increase along the midline **150** from one end to the other, may increase from the forward end to the rear, or may increase from the rear forward. In some embodiments, the thickness may increase across the width of the arch shell. For example, the thickness may be greatest at the center, greatest at the lateral edge, greatest at the medial edge, or greatest at both edges.

[0060] The thickness of midfoot portion **120**—the combination of base layer **102** and arch shell **140** in midfoot portion **120**—at the maximum height **126** of midfoot portion **120** may range from about 4 mm to about 15 mm, from about 5 mm to about 13 mm, from about 6 mm to about 11 mm or more preferably, from about 6 mm to about 9 mm. The thickness may be no more than 20 mm, no more than 18 mm, no more than 16 mm, no more than 14 mm, no more than 12 mm, no more than 11 mm, no more than 10 mm, no more than 9.5 mm, no more than 9 mm, no more than 8 mm, no more than 7 mm, no more than 6 mm, or no more than 5 mm. The thickness may be no less than 2 mm, no less than 5 mm, no less than 6 mm, no less than 7 mm, no less than 8 mm, no less than 9 mm, no less than 10 mm, or no less than 12 mm.

[0061] The arch area of insole **100**—the combination of base layer **102** and arch shell **140**—may have a flexural stiffness in the range between about 5 and 25 pounds/inch, preferably in the range between about 10 and 20 pounds/inch and, more preferably, in the range between about 8 and 18 pounds/inch. In some embodiments, the flexural stiffness is no greater than 25 pounds/inch, no greater than 20 pounds/inch, no greater than 18 pounds/inch, no greater than 17 pounds/inch, no greater than 15 pounds/inch, no greater than 13 pounds/inch, no greater than 12 pounds/inch, no greater than 11 pounds/inch, or no greater than 10 pounds/inch. In some embodiments, the flexural stiffness is no less than 7 pounds/inch, no less than 8 pounds/inch, no less than 9 pounds/inch, no less than 10 pounds/inch, no less than 12 pounds/inch, no less than 14 pounds/inch, no less than 15 pounds/inch, or no less than 18 pounds/inch.

[0062] The flexural stiffness may be dependent upon the size of the insole. For example, the flexural stiffness of an average women's size insole may be less than the flexural stiffness of an average men's size due at least partially to the smaller size of the insole. The difference may also be a function of reduced thicknesses of one or more components, including the base layer and the arch shell. In some embodiments, the flexural stiffness of an average women's size may be less than the flexural stiffness of an average men's size by about 20 to 80 percent, by about 30 to 70 percent, or by about 50 to 65 percent.

[0063] The method for determining flexural stiffness values above is in accordance with the three-point loading flexure test of ASTM D7264, with a flexure span of 7 cm and a 10 mm flexure deflection. The testing was conducted using an INSTRON™ compression strength testing machine, sold by Instron Corporation of Canton, Mass. U.S.A. Insoles **100** were placed in the platform of the test machine, equipped with a 50 pound (22.7 Kg) load cell. The insole was placed on two support bars that extended perpendicularly to the midline of the insole such that the support bars were even positioned beneath the arch shell along the midline **150**, and the loading bar contacted the insole from above along a line extending perpendicularly to the midline (and parallel to the support bars). Measurements of the amount of applied load required to deflect the central area of the insole arch 10 mm were recorded. For purposes of this disclosure, flexural stiffness is defined as the ratio of the applied load to the corresponding amount of arch deflection (designated by parameter "m" in ASTM D7264).

Evaluation of Exemplary Insole Embodiment on Wearers with Plantar Fasciitis Pain

[0064] The performance of an exemplary embodiment of the plantar fasciitis pain relief insole was evaluated on test subjects experiencing plantar fasciitis pain. The configuration of the exemplary embodiment and the results of the evaluation are provided below.

[0065] The exemplary embodiment is generally configured as shown in FIGS. **1-11**. The embodiment includes a base layer of SEBS and EVS and an arch shell of TPU. The men's sizing of this embodiment includes, along the midline **150** of the insole, a forefoot portion thickness of about 4-5 mm, a heel portion thickness at the center of the heel portion of about 7-9 mm, and a midfoot portion thickness of about 7-9 mm. The heel insert thickness is about 1 mm and the arch shell thickness of about 1 mm. The maximum height of the midfoot portion (the upper surface) from bottom planar surface **124** along the midline **150** of the insole is about 13-15 mm. The length of the arch shell **140** along the midline **150** is about 75-80 mm. The width of the arch shell **140** across the foremost portion of the arch shell **140** is about 73-76 mm. The width of the rearmost portion of the arch shell **140** is about 55-57 mm. The narrowest portion of the arch shell is about 53-56 mm, which is at a location along the midline that is about 6 mm from the rearmost portion of the arch shell that intersects the midline **150**. The maximum height of the bottom surface of the arch shell from bottom planar surface **124** along midline **150** is about 4-6 mm.

[0066] The women's sizing of this embodiment includes, along the midline **150** of the insole, a forefoot portion thickness of about 3-4 mm, a heel portion thickness at the center of the heel portion of about 6-8 mm, and a midfoot portion thickness of about 6-8 mm. The heel insert thickness is about 1 mm and the arch shell thickness is about 1 mm. The maximum height of the midfoot portion (the upper surface) from bottom planar surface **124** along the midline **150** of the insole is about 11-12 mm. The length of the arch shell **140** along the midline **150** is about 64-68 mm. The width of the arch shell **140** across the foremost portion of the arch shell **140** is about 62-65 mm. The width of the rearmost portion of the arch shell **140** is about 47-49 mm. The narrowest portion of the arch shell is about 47-49 mm, which is at a location along the midline that is about 5 mm from the rearmost portion of the arch shell that intersects the midline **150**. The maximum height of the bottom surface of the arch shell from bottom planar surface **124** along midline **150** is about 3-5 mm.

[0067] Arch stiffness data of the plantar fasciitis pain relief insole according to the embodiment described above as measured by a flexure test with a flexure span of 7 cm, in accordance with the ASTM 07264 three-point loading flexure test, is provided in Table 1 below. Also included in Table 1, for comparison, is the arch stiffness data for insoles of the same configuration described above except lacking the arch shell. The insole's midfoot arch section, with the insole in its in-use orientation, is subjected to a 10 mm flexure deflection during the arch stiffness test.

TABLE 1

Arch flexural stiffness of exemplary embodiment (men's and women's sizes)

Insole	Arch stiffness (lb/inch)
Plantar fasciitis pain relief insole with arch shell - Men's	16.7
Plantar fasciitis pain relief insole with arch shell - Women's	10.8
Insole without arch shell - Men's	8.6
Insole without arch shell - Women's	6.2

[0068] Comparing the results for the insoles with the arch shell to the insoles without arch shells shows the effect of the insert in significantly increasing arch stiffness. The amount of the increase is unexpected for such a thin insert and reflects a layering effect of the SEBS base layer and TPU arch shell, as well as the shape and contouring of the arch shell.

[0069] Relief of plantar fasciitis pain by using this exemplary insole embodiment was evaluated using a visual analogue scale (VAS) measurement. Forty-six men and forty-six women were evaluated over a span of six weeks. Participants wore the insoles for about eight hours per day. The results of the evaluation are provided in Table 2 below. A value of zero on the scale used for the evaluation corresponds to no pain, a value of 50 corresponds to moderate pain, and a value of 100 corresponds to the worst possible pain. Typically, pain associated with a value of about 60 cannot be ignored and the sufferer will seek relief, but may not seek professional treatment. Also included in Table 2 is the percentage pain reduction relative to baseline.

TABLE 2

Visual Analog Scale (VAS) Pain Values and Pain Reduction for all test subjects

	Baseline	Immediate	Day 1	Week 1	Week 2	Week 4	Week 6
Pain value (100 scale)	57.9	42.9	42.8	37.2	31.3	24.5	18.6
% Pain Reduction	0	27.4	26.4	36.4	46.2	58.5	68.1

[0070] The effectiveness of the insole in reducing wearer pain associated with plantar fasciitis reduction is clearly demonstrated by the reduction of pain value from 57.9 at baseline to 18.6 at the end of the 6-week treatment (six weeks of insole wearing).

[0071] Sufferers of plantar fasciitis typically experience plantar fasciitis heel pain upon the first arising from bed in the morning, the so called "morning plantar pain." The data of incidence of morning plantar fasciitis pain for all the ninety-two test subjects over six weeks of wearing the insole are listed in Table 3 below.

TABLE 3

Percentage incidence of morning plantar fasciitis pain while wearing the insole							
	Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
% Incidence	87	77	69	64	57	54	51

[0072] The data clearly demonstrates a 36% reduction in the incidence of morning plantar fasciitis heel pain after six weeks of insole wearing.

[0073] Thus, with the present invention, insole **100** provides a low profile insole that can provide the ideal balance between arch support and flexibility for wearer's experience plantar fasciitis pain. The arch stiffness of insole **100** is high enough to reduce the arch flattening associated with plantar fasciitis while being low enough to not provide an overly stiff arch that would irritate the plantar fascia and cause pain. As described above, the thinness of the arch shell provided a surprising benefit to wearers with plantar fasciitis. It was thought that a shell of such thinness would have little or no effect on easing plantar fasciitis pain relative to an insole of similar overall thickness but lacking the shell. However, it was discovered that the arch shell, layered with the base layer, provided just enough arch support that pain associated with plantar fasciitis reduce significantly. Because of its low profile, insole **100** can be inserted in any footwear, even those with built-in arch supports, without introducing excessive bulk under the foot that, even for wearers without plantar fasciitis, can cause discomfort.

[0074] U.S. Pat. No. 6,915,598 described a third-quarter length insole with arch spring insert which provided added arch support. This arch spring insert has a thickness of about 2 mm, and is made of fiberglass filled polypropylene (Dr. Scholl's Tri-Comfort insole). In contrast to the TPU arch shell described above, this arch spring insert has a significantly higher flexural stiffness (Table 4). The method for determining flexural stiffness values for the arch shells is the same as described above, in accordance with the three-point loading flexure test of ASTM D7264.

TABLE 4

Flexural stiffness of arch shell compared to arch spring insert of Dr. Scholl's Tri-Comfort insole	
Material	Flexural Stiffness, lb/in
M's Plantar Fasciitis Insole (arch shell)	0.97
Wm's Plantar Fasciitis Insole (arch shell)	0.92
U.S. Pat. No. 6,915,598 (disclosure)	5 to 60

[0075] Although the present invention uses the term "insole," it will be appreciated that the use of other equivalent or similar terms such as "innersole" or "insert" are considered to be synonymous and interchangeable, and thereby, they are included in the presently claimed invention.

[0076] Further, although the present invention has been described primarily in connection with removable insoles, the invention can be incorporated directly into the sole of a shoe, and the present invention is intended to cover the same. In this regard, reference is made in the claims to an insole for use with footwear, including a removable insole or an insole built into a shoe. If built into a shoe, for example, the heel portion could be fixed and the mid portion and forefoot portions could be allowed to elongate as the foot flexes.

[0077] The foregoing description, for the purpose of explanation, has been described with reference to specific embodiments. However, the illustrative discussions above are not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations are possible in view of the above teachings. The embodiments were chosen and described in order to best explain the principles of the techniques and their practical applications. Others skilled in the art are thereby enabled to best utilize the techniques and various embodiments with various modifications as are suited to the particular use contemplated.

[0078] Although the disclosure and examples have been fully described with reference to the accompanying figures, it is to be noted that various changes and modifications will become apparent to those skilled in the art. Such changes and modifications are to be understood as being included within the scope of the disclosure and examples as defined by the claims. Finally, the entire disclosure of the patents and publications referred to in this application are hereby incorporated herein by reference.

1. An insole for insertion into footwear, comprising:
a base layer extending through a forefoot portion, a midfoot portion, and a heel portion of the insole; and
an arch shell in the midfoot portion of the insole beneath the base layer, wherein the arch shell has a thickness of no more than 2 mm.

2. The insole of claim **1**, wherein the midfoot portion of the insole comprises a flexural stiffness of 25 pounds per inch or less.

3. The insole of claim **1**, wherein the midfoot portion of the insole comprises a flexural stiffness of 8 pounds per inch or more.

4. The insole of claim **1**, wherein the insole is configured such that the forefoot portion of the insole extends at least to distal ends of metatarsals of a foot.

5. The insole of claim **1**, wherein the heel portion is a cupped heel portion.

6. The insole of claim **1**, wherein in the midfoot portion, the base layer comprises an upwardly extending contour for supporting a foot arch.

7. The insole of claim **1**, wherein the forefoot portion has at least a first thickness and the midfoot portion has at least a second thickness that is greater than the first thickness.

8. The insole of claim **1**, wherein the base layer comprises a material having a first hardness and the arch shell comprises a material having a second hardness that is greater than the first hardness.

9. The insole of claim **1**, wherein the arch shell has a constant thickness.

10. The insole of claim **1**, comprising a heel insert in the heel portion.

11. The insole of claim **10**, wherein the arch shell comprises at least one extension located at least partially along the heel portion rearward of the forewardmost portion of the heel insert.

12. The insole of claim **1**, comprising a cover layer on at least a portion of an upper surface of the base layer.

13. The insole of claim **1**, wherein the insole is a removable insole for insertion into footwear.

14. An insole for insertion into footwear, comprising:

a base layer extending through a forefoot portion, a midfoot portion, and a heel portion of the insole; and

an arch shell in the midfoot portion of the insole beneath the base layer,

wherein the midfoot portion of the insole comprises a flexural stiffness of 25 pounds per inch or less.

15. The insole of claim **14**, wherein the midfoot portion comprises a flexural stiffness of 8 pounds per inch or more.

16. The insole of claim **14**, wherein the insole is configured such that the forefoot portion extends at least to distal ends of metatarsals of a foot.

17. The insole of claim **14**, wherein the heel portion is a cupped heel portion.

18. The insole of claim **14**, wherein in the midfoot portion, the base layer comprises an upwardly extending contour for supporting a foot arch.

19. The insole of claim **14**, wherein the forefoot portion has at least a first thickness and the midfoot portion has at least a second thickness that is greater than the first thickness.

20. The insole of claim **14**, wherein the base layer comprises a material having a first hardness and the arch shell comprises a material having a second hardness that is greater than the first hardness.

21. The insole of claim **14**, wherein the arch shell has a constant thickness.

22. The insole of claim **14**, comprising a heel insert in the heel portion.

23. The insole of claim **22**, wherein the arch shell comprises at least one extension located at least partially along the heel portion rearward of the forewardmost portion of the heel insert.

24. The insole of claim **14**, comprising a cover layer on at least a portion of an upper surface of the base layer.

25. The insole of claim **14**, wherein the insole is a removable insole for insertion into footwear.

26. A set of removable insoles comprising:

at least one removable insole comprising:

a base layer extending through a forefoot portion, a midfoot portion, and a heel portion of the insole; and

an arch shell in the midfoot portion of the insole beneath the base layer, wherein the arch shell has a thickness of no more than 2 mm.

27. The set of insoles of claim **26**, comprising instructions for using the set of removable insoles for relieving plantar fasciitis pain.

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