A43B 7/22 (2006.01) A61F 5/14 (2006.01)

Title: MULTI-PLUG DESIGN SHOE INSOLE

Abstract: An insole is provided for reducing peak plantar pressure on a foot. The insole includes a compressible pad having a plurality of holes extending from a bottom surface of the compressible pad and partially through the compressible pad. A plurality of compressible plugs is disposed in the plurality of holes, wherein the plurality of compressible plugs has a stiffness that is different than a stiffness of the compressible pad. The plurality of compressible plugs is concentrated in a reduced stiffness portion of the compressible pad that substantially corresponds to an area of peak plantar pressure on the foot.

FIG. 1

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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MULTI-PLUG DESIGN SHOE INSOLE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. provisional application 60/957,238 filed August 22, 2007, which is hereby incorporated in its entirely.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] This invention was made with Government support under contract 2R01 (HD036895-04A1) awarded by the U.S. National Institute for Health, National Institute for Child Health and Human Development and National Center for Medical Rehabilitation Research.

APPENDIX


BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

[0004] The present invention is in the field of therapeutic footwear and specifically relates to the design of insoles that may be custom-formed or mass-produced.

RELATED ART

[0005] High peak plantar pressures (PPP) during walking can contribute to painful forefoot syndromes, such as metatarsalgia, in otherwise healthy people, and to skin breakdown in people with conditions such as diabetes and peripheral neuropathy. Peripheral neuropathy is a common underlying cause of foot ulcers in the diabetic patient because the lack of painful feedback allows unnoticed repetitive tissue injury to occur. During walking, normal and shear stresses develop which may lead to serious damage in the neuropathic foot. Normal
stresses originate by the repetitive vertical pressure on the foot while shear stresses occur when deep tissue slides under superficial tissue.

Some previous insole designs have attempted to reduce PPP by providing single plugs that are softer than the surrounding insole and that penetrate the full thickness of the insole. However, when a single soft plug is inserted through an insole, the softer material is in direct contact with the foot, which may create localized high PPP because of the stiffness discontinuity at the boundary between the softer plug and the rest of the insole. Such designs also lack flexibility to be able to distribute high, damaging pressure in a custom and specific manner.

SUMMARY OF THE INVENTION

The present invention is a therapeutic insole having a compressible pad with multiple compressible plugs disposed therein. The compressible plugs are preferably arranged within the compressible pad to reduce PPP and to limit the occurrence of secondary pressure peaks arising at the boundary regions between materials having different stiffnesses. Optimal plug configurations may be determined by various methods such as numerical analysis, empirical testing, and/or combinations of the two. Generic insoles for the general population could be developed based on the typical pressure distribution of the foot, and the insole designs of the present invention can be applied to footwear for the general population as well as persons who suffer from conditions which cause foot pain.

Further areas of applicability of the present invention will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating the preferred embodiment of the
invention, are intended for purposes of illustration only and are not intended to limit the scope of
the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The present invention will become more fully understood from the
detailed description and the accompanying drawings, wherein:

[0010] Figure 1 illustrates a bottom view of a therapeutic insole according to an
embodiment of the invention.

[0011] Figure 2 illustrates a two-dimensional model of a foot in the sagittal plane
supported by an insole and sole.

[0012] Figure 3 is a chart providing a comparison between data resulting from a
numerical analysis and an empirical test.

[0013] Figure 4 is a chart providing results from a numerical analysis comparing
several types of inserts.

[0014] Figure 5 is a chart providing results from a numerical analysis comparing
several configurations of cylindrical plugs.

[0015] Figure 6 illustrates a pressure reading of a foot corresponding to the late
stance phase of walking.

[0016] Figure 7 illustrates a bottom view of an insole having a localized plug
configuration.

[0017] Figure 8 illustrates a bottom view of an insole having a global plug
configuration.

[0018] Figure 9 illustrates a bottom view of an insole having single sheet insert.
[00019] Figure 10 illustrates a sectional view of an alternate embodiment of an insole having plugs of different stiffness.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00020] The following description of the preferred embodiment(s) is merely exemplary in nature and is in no way intended to limit the invention, its application, or uses.

[00021] As illustrated in Figure 1, an insole 20 is provided to cushion the bottom surface of a foot F. The insole 20 comprises a compressible pad 22 having a plurality of holes 24 extending at least partially therethrough. A plurality of compressible plugs 26 is disposed in the plurality of holes 24. The plugs 26 preferably have a stiffness $S_1$ that is different than a stiffness $S_2$ of the compressible pad 22 such that the stiffness of the insole 20 varies in the areas in which the plugs 26 are disposed in the holes 24. In one embodiment, plugs 26 of different stiffness are combined in patterns that redistribute pressure.

[00022] The compressible pad 22 may be constructed of any suitable material, and may be designed to provide cushioning to all or a portion of the bottom surface of a foot F. The plugs 26 may also be constructed of any suitable material providing a desired stiffness.

[00023] As shown in Fig. 2 the holes 24 in the compressible pad 22 and the plugs 26 disposed therein preferably do not extend through an entire thickness $T$ of the compressible pad 22. For example, the plugs preferably extend from a bottom surface 28 of the compressible pad 22 through a portion 30 of the full thickness $T$ of the compressible pad 22 to reduce secondary pressure peaks at the boundaries between the plugs 26 and the compressible pad 22. In a preferred embodiment, each hole 24 extends from the bottom surface 28 of the compressible pad 22 through approximately fifty to eighty percent of the compressible pad's thickness $T$. 


The plugs 26 may be arranged within the compressible pad 22 according to various configurations. The plugs 26 may also be many different shapes and sizes. Preferably the plugs 26 are cylindrical and have a diameter D in the range of approximately one to six millimeters, which would result in a range of horizontal cross-sectional areas of approximately one to twenty-nine square millimeters. In the exemplary embodiment, the plugs 26 are spaced approximately one to five millimeters apart. Accordingly, it will be appreciated that plugs 26 of different shapes would have effective diameters equivalent to the circular shape to produce corresponding plug areas. However, it is not required that the plugs 26 be cylindrical. Preferably, the plugs 26 are sized, shaped and configured within the compressible pad in a manner that reduces peak plantar pressures (PPP) while limiting the occurrence of secondary pressure peaks, such as those that may arise at boundaries between regions of varying stiffness.

In one embodiment, shown in Figure 10, the compressible pad 22 includes a reduced stiffness portion 32 that corresponds to an area of PPP 40 on the foot F and is disposed in a forefoot portion 34 of the compressible pad 22. For example, the reduced stiffness portion 32 of the compressible pad 22 may be configured to position under a metatarsal head MH of the foot F. The plurality of compressible plugs 26 is disposed within the reduced stiffness portion 32. In one embodiment, a first plurality 36 of compressible plugs 26 having a stiffness S3 greater than the stiffness of the compressible pad 22 is disposed in a plurality of holes 24 peripheral to the reduced stiffness portion 32 of the compressible pad 22. A second plurality 38 of compressible plugs 26 having a stiffness S4 that is less than the stiffness of the compressible pad 22 is disposed in a plurality of holes 24 throughout the reduced stiffness portion 32 of the compressible pad 22.
Exemplary Numerical Analysis

[00026] Various methods may be used to determine optimal arrangements of the plugs 26 within the compressible pad 22. One such method is numerical analysis, or more specifically finite element analysis. According to an exemplary numerical analysis, the structure of a foot F used for a finite element model is generated from Spiral X-ray Computed Tomography (SXCT) image data acquired while a subject is seated in a loading device and a load of fifty percent of body weight is applied to the forefoot. Boundary coordinates are preferably extracted from the SXCT data using an Analyze software system and the pressure distribution is preferably measured using an F-Scan system (Tekscan, South Boston, MA) with a pressure sensor taped to the plantar aspect of the subject's foot F.

[00027] According to this analysis, the structure of the foot F is characterized by bone, cartilage, flexor tendon, fascia and tissue. Figure 2 shows an individual two-dimensional model in the sagittal plane as developed for metatarsals 2 and 3 in the simulated push-off position using the finite element analysis program StressCheck (Engineering Software Research & Development, Inc., St. Louis, MO).

[00028] The linear elastic material properties used in this exemplary analysis are $E = 7300$ MPa for bones, $E = 10$ MPa for cartilage, $E = 15$ MPa for a flexor tendon, and $E = 85$ MPa for fascia. Muscle and fat may be grouped into a single material type (tissue) with nonlinear elastic properties characterized by the strain energy density function:

$$W = W_L e^{2C\epsilon}, \quad W_L = \frac{1}{2} \{\epsilon\}^T \{D\} \{\epsilon\}$$

[00029] According to this equation, $W$ is the strain energy density, $W_L$ is the linear strain energy, $C$ is a constant, $\epsilon$ is the base of the natural logarithm, $\{D\}$ is the linear stiffness matrix and $\{\epsilon\}$ is the strain tensor. This strain energy density function depends on three parameters: $E$ (slope of the one-dimensional stress-strain curve at $\epsilon=0$), $\nu$ (Poisson's ratio), and $C$.
The values preferably used for the material coefficients are £=0.30 MPa, C=60 MPa⁻¹, \( \nu \)=0.45.

Nonlinear material properties are preferably specified for the standard TCI (#2 plastizote), the plugs (Poron®) and shoe sole (rubber). The material properties for the rubber and plastizote may be obtained by compression testing of samples taken from the shoe sole and compressible pad 22 utilizing an Instron testing machine (Wilson Instruments, Canton, MA) and following the procedures described in the ASTM standard D575-91, while those of Poron® may be obtained from literature.

For the TCI and plugs 26, a 5-parameter nonlinear material description is preferably used, characterized by the slope of the initial linear portion (\( E_i \)), the Poisson's ratio (\( \nu \)), the strain at the end of the linear range (\( \varepsilon_i \)), the slope of a second linear region (\( E_t \)), the starting point on the second linear part of the stress-strain relationship given by the strain (\( \varepsilon_2 \)) and the corresponding stress (\( \sigma_2 \)). The stress-strain law is linear for strains less than \( \varepsilon_i \) and for strains greater than \( \varepsilon_2 \). The two linear segments may be joined by a cubic spline. In this exemplary analysis the following values are used for the #2 plastizote: \( E=1.75 \) MPa, \( E_t=0.0175 \) MPa, \( \varepsilon_i=0.046 \), \( \varepsilon_2=0.2 \), \( \sigma_2=0.105 \) MPa, \( \nu=0.2 \), and Poron®: \( E=0.80 \) MPa, \( E_t=0.13 \) MPa, \( \varepsilon_i=0.031 \), \( \varepsilon_2=0.1 \), \( \sigma_2=0.05 \) MPa, \( \nu=0.3 \). For the shoe sole, the strain energy density function set forth above was used with values: \( E=1.25 \) MPa, \( C=25 \) MPa⁻¹, \( \nu \)=0.45.

In the present numerical model, a compression load is applied to the tibia and a moment is added to incorporate the compensating effect of the Achilles tendon (not included in the model). Furthermore the flexor tendon is preferably pre-stressed to represent typical values for the Flexor Digitorum Longus during push-off.

A finite element mesh density is preferably selected to capture the topological complexity of the model and frictionless contact condition may be specified between
the foot F and the TCI. According to this analysis, the elements representing the TCI are directly connected to those representing the sole of the shoe, and the shoe is supported with a compression-only elastic foundation (no friction) with an elastic constant selected to represent the stiffness of the support plate in the loading device. Plane strain conditions may be assumed.

[00034] The numerical solution is obtained by increasing the polynomial degree of elements (p-level) on a fixed mesh. Preferably a sequence of contact solutions is obtained for several p-levels until the estimated relative error in energy norm is small (under 2%), followed by a nonlinear analysis to incorporate the effects of material nonlinearities and subsequent modification of the contact. For the model validation, the pressure distribution for the barefoot and standard condition footwear of a subject may be obtained from the FEA model and compared with the pressure distribution obtained from the F-Scan system.

[00035] As noted above, the F-Scan pressure recording is preferably made while the subject is sitting in the loading device and applying a load of 50% of body weight to their forefoot. It is intended that the forefoot pressure distribution collected with the subject sitting on the loading device be similar to the forefoot pressure distribution at the push-off phase of walking (80% of stance phase).

[00036] Figure 3, which illustrates the pressure distribution for the 2nd ray - barefoot and footwear conditions - measured and calculated (r=0.83 for barefoot and r=0.95 for shoe and TCI), indicates that the results of the FEA model, as described above, (2nd ray loaded with 75 N) and experimental pressure testing, as described in greater detail below, are in good agreement.

[00037] According to this exemplary analysis, in order to determine an optimal TCI design, the numerical analyses are repeated modifying the TCI by inserting a number of Poron® plugs 26 of different sizes. The results of each numerical TCI alteration can be
compared with those obtained using a standard TCI without any plugs to determine which design provides the greatest PPP reduction while limiting secondary pressure peaks.

[00038] Figure 4 shows FEA results of pressure distribution 35-mm proximal and 30-mm distal from the center of a metatarsal head MH of the 2nd ray of a subject loaded with 62N and for four conditions: standard plastizote TCI, TCI with 7 Poron® plugs (cylinders), TCI with a single partial penetration Poron® plug (Box) and TCI with a complete penetration Poron® plug (Plug). While the single plug design (PPP=106 kPa for Plug, PPP=107 kPa for Box) provides similar pressure reduction compared to the multi-plug design (PPP=10 kPa), the single plug designs produce an undesirable secondary pressure peak 20-mm distally from the center of the metatarsal head MH at the end of the plug 26.

[00039] Figure 5 shows FEA results of pressure distribution 35-mm proximal and 30-mm distal from the center of the metatarsal head MH of the 2nd ray of the diabetic subject for four conditions: standard plastizote TCI, TCI with 7 Poron® plugs (7 cylinders), 8 Poron® plugs (8-cylinders) and 9 Poron® plugs (9 cylinders). In all the conditions using plugs 26, one plug 26 is located at the position of the PPP for the standard TCI, and three plugs 26 are placed proximally from it and 3, 4 or 5 plugs are placed distally to complete the design. The results show that the 7-plug design is more effective in reducing the PPP compared to the TCI alone, and that adding more plugs 26 distally reduces the secondary peak observed at about 20-mm distally from the center of the metatarsal head MH compared to the single plug design.

Exemplary Empirical Test

[00040] Designs of plug configurations optimized by FEA may be further validated and compared with other designs by empirical testing. According to an exemplary method for empirically testing such designs, a set of insoles is constructed to fit a first test subject (47 years old, 165 lb), with a history of forefoot pain (metatarsalgia), and a second test
subject with a history of diabetes and peripheral neuropathy (68 years old, 176 lb, 44 years of DM). Both subjects experience high localized pressures in the forefoot.

[00041] First, a custom TCI insole 20 of standard plastizote material, about 10-mm thick in the region of the metatarsal heads MH, is made to fit both the left and right feet of each subject. A certified pedorthist and orthotist then takes a foam impression of a subject's foot F to make a positive plaster model of their foot F. The foam is preferably compressed 2-4 cm to capture the entire impression of the foot F and medial longitudinal arch. The TCI is preferably made from a base of 1.27 cm (1/2") #2 plastizote with a shore value of approximately 35 and heightened to include the medial longitudinal arch fabricated to fit inside the shoe.

[00042] According to this exemplary method, a trial in-shoe pressure assessment using an F-Scan system is then performed with the subjects wearing the unmodified standard TCI and standard shoes. From the F-scan pressure reading corresponding to the late stance phase of walking (the highest pressure in the forefoot region as shown in Figs. 6a and 6b) and based on the results of the numerical studies discussed above, a Poron® plug pattern is used extending approximately 15-mm proximally, distally, laterally and medially from the location of the PPP. The softer plugs 26 used in this exemplary method were cylindrical, 4-mm in diameter, spaced 1-mm apart extending in all direction around the point of PPP, and penetrated 7-mm into the TCI. This configuration is shown in Figs. 7a and 7b for the first and second test subjects, respectively. The locations of the plugs 26 were determined from the pressure readings and not from the location of the metatarsal heads MH.

[00043] Two additional patterns are also tested according to this exemplary method: one in which soft plugs 26 are placed throughout the entire forefoot region, as shown in Figs. 8a and 8b for the first and second test subjects, respectively, and another in which a single
7-mm thick sheet of Poron® is used in the forefoot region, as shown in Figs. 9a and 9b for the first and second test subjects, respectively.

[00044] According to this exemplary method, plantar pressures are recorded during walking in all 4 insole conditions: no plugs 26, localized plugs 26 (Fig. 7), global plugs 26 (Fig. 8), and single sheet (Fig. 9) using the F-Scan system. A new F-scan pressure sensor is preferably cut to fit the shoe of each subject, and a pressure sensor is placed in the footwear over the insole 20 and under the plantar foot F. Both subjects preferably wear SoleTech shoes (style E3010). For the purposes of this exemplary method, data is preferably collected at 50 Hz during 6 walking trials, a mean of 3 representative steps (not highest or lowest) is chosen during the mid portion of each walking trial, and a mean of the 18 steps is used for the peak pressure.

[00045] Table 1 below shows the average PPP for the four different regions of the forefoot (as shown in Fig. 6a) and four different TCI conditions obtained from the F-Scan measurements for the first subject, according to this exemplary method.

<table>
<thead>
<tr>
<th>Insole</th>
<th>Peak pressure (PP in kPa), standard deviation (STD in kPa) and % change in PPP (ΔP) from TCI alone</th>
<th>Great toe</th>
<th>Medial</th>
<th>Middle</th>
<th>Lateral</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>PPP</td>
<td>STD</td>
<td>ΔP</td>
<td>PPP</td>
</tr>
<tr>
<td>Standard TCI</td>
<td></td>
<td>337</td>
<td>66</td>
<td>---</td>
<td>176</td>
</tr>
<tr>
<td>Local plug</td>
<td></td>
<td>347</td>
<td>85</td>
<td>3.0</td>
<td>156</td>
</tr>
<tr>
<td>Global plug</td>
<td></td>
<td>341</td>
<td>60</td>
<td>1.2</td>
<td>149</td>
</tr>
<tr>
<td>Inlay</td>
<td></td>
<td>391</td>
<td>73</td>
<td>16.0</td>
<td>158</td>
</tr>
</tbody>
</table>

Table 1: Peak plantar pressure (PPP) for different regions of the forefoot of the first subject from the F-Scan measurements. Average PP and standard deviation (STD) values over 18 steps.

[00046] The PPP and standard deviation (STD) values are averages over 18 steps. The last column in each region shows the percent change in pressure (ΔP) over that of the TCI alone (a positive number indicates a pressure increase, while a negative number a reduction in pressure). While each of the designs reduce PPP in the middle region (where initial PPP is highest and the subject had a history of pain) these results show that the local plug 26 is the most effective in reducing the PPP in this targeted region (13.6% reduction from 427 kPa to 369 kPa).
The local plug design also shows a reduction of PPP in the medial region of 11.4%, with a small increase in pressure in the lateral and great toe regions (4.6% and 3%, respectively).

[00047] Table 2 below shows the same information obtained for the second subject according to this exemplary method.

<table>
<thead>
<tr>
<th>Insole</th>
<th>Peak pressure (PP in kPa), standard deviation (STD in kPa) and % change in PP (ΔP) from TCI alone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Great toe</td>
</tr>
<tr>
<td></td>
<td>PP</td>
</tr>
<tr>
<td>Standard TCI</td>
<td>168</td>
</tr>
<tr>
<td>Local plug</td>
<td>198</td>
</tr>
<tr>
<td>Global plug</td>
<td>224</td>
</tr>
<tr>
<td>Inlay</td>
<td>202</td>
</tr>
</tbody>
</table>

Table 2: Peak pressure (PP) for four different regions of the forefoot of the second subject from the F-Scan measurements. Average PP and standard deviation (STD) values over 18 steps.

[00048] In the case of the second subject, the global plug and the local plug designs show a reduction in the PPP occurring in the middle and lateral regions (3.3-24.5%), while the inlay is not effective. There is a pressure increase in the great toe and medial regions for all three plug configurations, but the pressure for the standard TCI is less than in the other two regions.

[00049] Table 3 below shows a summary of the PPP for the middle region of the forefoot from the F-Scan measurements for the two subjects and for the four different TCI conditions. The change in pressure (ΔP) is indicated for each case, and both subjects show decrease in the PPP for the two plug designs.

<table>
<thead>
<tr>
<th>Insole</th>
<th>Peak pressure (PP in kPa) and % change in PP (ΔP) from TCI alone in the region Middle</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First subject</td>
</tr>
<tr>
<td></td>
<td>PPP</td>
</tr>
<tr>
<td>Standard TCI</td>
<td>427</td>
</tr>
<tr>
<td>Local plug</td>
<td>369</td>
</tr>
<tr>
<td>Global plug</td>
<td>386</td>
</tr>
<tr>
<td>Inlay</td>
<td>402</td>
</tr>
</tbody>
</table>

Table 3: Peak plantar pressure (PPP) for Middle region of the forefoot from the F-Scan measurements. Average PPP values over 18 steps. First and second subjects.
Plugs of Varying Stiffness

[00050] In an alternative embodiment of the invention, plugs 26 of varying stiffnesses are inserted into different regions of the compressible pad 22, as opposed to those embodiments discussed above in which the stiffness of the plugs 26 is uniform. As shown in Figure 10, a first plurality 36 of compressible plugs 26 having a stiffness $S_3$ that is greater than the stiffness of the compressible pad 22 is disposed in regions of the compressible pad 22 peripheral to those regions of the foot F experiencing PPP. Further, a second plurality 38 of compressible plugs 26 having a stiffness $S_4$ that is less than the stiffness of the compressible pad 22 is disposed in holes 24 in the regions of the compressible pad 22 corresponding to regions of the foot F experiencing PPP. In such cases, the first plurality 36 of compressible plugs 26 can help to redistribute pressure away from areas of PPP. By providing plugs 26 of varying stiffness, an additional degree of customization is available in the design of the insole 20.

[00051] As various modifications could be made to the exemplary embodiments, as described above with reference to the corresponding illustrations, without departing from the scope of the invention, it is intended that all matter contained in the foregoing description and shown in the accompanying drawings shall be interpreted as illustrative rather than limiting. Thus, the breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims appended hereto and their equivalents.

[00052] It will also be appreciated that insoles 20 with standardized plug designs can be designed and mass-produced for the general population based on typical pressure distributions of the foot F. Accordingly, for such standardized plug designs, the analysis of typical pressure distributions may be made by a similar finite element model methodology or any
other suitable experimental or empirical technique. Generally, typical patterns of the plug designs are substantially circular and/or oval shapes having an effective diameter of approximately thirty to forty millimeters. However, the shape of a particular plug design pattern may be irregular if the peak plantar pressures are irregular. Also, it should be appreciated that the plug design patterns can be used to alleviate pressure anywhere in the foot F. Although the forefoot is the most common location, the plugs 26 can be used to redistribute pressure in other regions of the foot F, such as at the heel.
CLAIMS

What is claimed is:

1. An insole for reducing plantar pressure on a portion of a foot, the insole comprising:

   a compressible pad having a stiffness;

   a plurality of holes disposed within said compressible pad; and

   a plurality of compressible plugs disposed in said plurality of holes, said plurality of compressible plugs having a different stiffness than said compressible pad.

2. The insole of claim 1, wherein each of said compressible plugs has a cross-sectional area in a transverse plane of approximately one to twenty-nine square millimeters, wherein said plurality of compressible plugs are substantially cylindrical, and wherein said each of said compressible plugs has an effective diameter of approximately 1mm to 6mm.

3. The insole of claim 1, wherein said plurality of holes are spaced approximately one to five millimeters apart.

4. The insole of claim 1, wherein said plurality of holes and said plurality of compressible plugs are concentrated in a reduced stiffness portion of said compressible pad.

5. The insole of claim 1, wherein each said hole extends from a bottom surface of said compressible pad and partially through said compressible pad.

6. The insole of claim 5, wherein each said hole extends from said bottom surface of said compressible pad through approximately fifty to eighty percent of a thickness of said compressible pad.

7. The insole of claim 1 further comprising a plurality of stiffer compressible plugs disposed in a plurality of holes peripheral to the reduced stiffness portion of said compressible pad, wherein said plurality of stiffer compressible plugs are stiffer than said plurality of compressible plugs.
8. The insole of claim 1, wherein said compressible pad comprises a reduced stiffness portion that corresponds to an area of peak plantar pressure on the foot, and the plurality of compressible plugs is disposed within the reduced stiffness portion.

9. The insole of claim 8, wherein said reduced stiffness portion is disposed in a forefoot portion of said compressible pad.

10. The insole of claim 9, wherein said reduced stiffness portion of said compressible pad is positioned under a metatarsal head of the foot.

11. The insole of claim 1, wherein said plurality of compressible plugs is arranged locally in a region of said compressible pad corresponding to an area of peak pressure on the foot.

12. An insole for reducing peak plantar pressure on a foot, the insole comprising:

   a compressible pad having a plurality of holes extending from a bottom surface of said compressible pad and partially through said compressible pad;

   a first plurality of compressible plugs having a stiffness greater than a stiffness of said compressible pad and disposed in a plurality of holes peripheral to a reduced stiffness portion of said compressible pad; and

   a second plurality of compressible plugs having a stiffness that is less than the stiffness of said compressible pad and disposed in a plurality of holes throughout said reduced stiffness portion of said compressible pad.

13. The insole of claim 12, wherein said plurality of compressible plugs are arranged in a substantially circular or oval pattern having a center that substantially corresponds to the center of an area of peak plantar pressure on the foot.

14. The insole of claim 13, wherein said pattern is positioned substantially under a metatarsal head of the foot.

15. The insole of claim 12, wherein said compressible plugs are substantially cylindrical.
16. The insole of claim 12, wherein each said hole extends from said bottom surface of said compressible pad through approximately fifty to eighty percent of a thickness of said compressible pad.

17. A method of reducing peak plantar pressure on a foot, said method comprising:

   providing a compressible pad having a plurality of holes extending therethrough;

   providing a plurality of compressible plugs disposed in the plurality of holes, the plurality of compressible plugs having a stiffness that is different than a stiffness of the compressible pad; and

   analyzing the foot to facilitate determining an optimal arrangement of the compressible plugs to create a reduced stiffness portion of the compressible pad.

18. The method of claim 17, wherein the optimal arrangement of the compressible plugs in the reduced stiffness portion relieves peak plantar pressure on the foot while avoiding substantial secondary pressure peaks.

19. The method of claim 17, wherein analyzing the foot further comprises positioning a subject in a sitting position with approximately half of the subject's weight on the subject's foot, and positioning a sensor on the plantar portion of the foot and wherein determining an optimal arrangement of the compressible plugs further comprises providing plugs having different stiffnesses.

20. The method of claim 19, wherein determining an optimal arrangement of the compressible plugs further comprises arranging a first plurality of plugs around a periphery of the reduced stiffness portion of the compressible pad, and arranging a second plurality of plugs within the reduced stiffness portion of the compressible pad.
**INTERNATIONAL SEARCH REPORT**

**A CLASSIFICATION OF SUBJECT MATTER**

IPC(8) - A43B 7/22; A61F 5/14 (2008.04)

USPC - 36/91, 154

According to International Patent Classification (IPC) or to both national classification and IPC

**B FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC(8)-A43B 7/22; A61F 5/14 (2008.04)

USPC-36/91 , 154

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC-36/88, 145

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWest(PGPB, USPT, EPAB, JPAB), USPTO, Google Scholar, Google Patent shoe, footwear, insoles, sole, innersole, cushion, plugs, pad, support, cylinder, therapeutic, healing, restorative, curative, rehabilitative, pressure, strain, tension, stress, stiffness, firmness, hole, opening, metatarsal, plantar, arch, caudal

**C DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
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<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 2004/0188354 A1 (Nguyen) 2 September 2004 (02 09 2004), (para [0024]-[0031]), Fig 1-6</td>
<td>1-20</td>
</tr>
<tr>
<td>Y</td>
<td>US 6,301,805 B1 (Howlett, et al ) 16 October 2001 (16 10 2001), Col 7, In 17-67, Col 8, In 1-7, Fig 1-2, 36, 38</td>
<td>1-20</td>
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<tr>
<td>Y</td>
<td>US 7,206,718 B2 (Cavanagh, et al ) 17 Aprt 2007 (17 04 2007), (Col 5, In 30-55, Col 6, In 57-67, Col 7, In 1-31, Fig 2, 4-7)</td>
<td>17-20</td>
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</table>

Further documents are listed in the continuation of Box C

* Special categories of cited documents

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search

21 October 2008 (21 10 2008)

Date of mailing of the international search report

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