DEVICE FOR PROVIDING SELF-ADJUSTABLE ARCH-SUPPORT AND METHOD MAKING THE SAME

Abstract: Device (1) for providing self-adjustable support for a user's foot. The device (1) includes an insole member (2). An inflatable bladder (3) is arranged on the insole member (2) and is configured to generally conform to a portion of the user's foot. An open cellular foam material (5) is arranged in an interior of the inflatable bladder (3). A valve (4) for controlling passage of air into and from the open cellular foam material (5) is contained in the interior of the inflatable bladder (3). A stiffener member (7) is arranged beneath the insole member (2) in an area of the inflatable bladder (3). A method of making a device (1) for providing self-adjustable support for a user is also provided. The method includes forming an inflatable bladder (3) on a support member (2), the inflatable bladder (3) being defined by a material layer of the support member (2) and a stiffener member (7) and comprising an open cellular foam material (5) arranged in an interior of the inflatable bladder (3) and mounting a valve (4) to a wall of the inflatable bladder (3).
1. The Field of the Invention

[0001] The present invention relates to orthotics and custom conformable devices, including custom fitting orthotics. The present invention also relates to a method of making an orthotic and a custom conformable device, including custom fitting orthotics.

2. Discussion of Background Information

[0002] Orthotics is the science of treating anatomical disorders, such as joint, bone, or muscle disorders, with anatomical supports, such as braces, inserts, and cushions. Anatomical supports have been commonly used both to increase comfort and to aid in medical treatments. For instance, arch supports have been used for many years for both added foot comfort when wearing shoes, and for treatment of foot and knee problems. Arch supports fall into one of two common categories: (1) inserts that increase padding or cushion; and (2) corrective devices, commonly referred to as orthotics, that correct foot position to relieve stress on the foot, knee or leg. Orthotics are commonly used to support feet with normal alignment, and to correct feet that have excessive pronation.

[0003] Pronation is the inward rotation of the middle part of the foot, and is commonly associated with a low arch. One function of orthotics is to prevent the natural pronation of the normal foot during walking. Three separate arches are described that support the weight of the body. These arches are not rigid and provide flexibility and leverage for walking. With normal walking, the foot lands in a supinated or high arch position at heel strike. As weight is accepted by the foot during walking, the arch flattens and the foot pronates until it is at maximum pronation and maximum load, approximately 25% of the way into the stance. The foot then resupinates until push off, when all weight is removed from the foot. One function of orthotics is to shorten the period of time in pronation during stance phase of gait to reduce stress on the tendons of the foot and knee. Orthotics should exert a gentle, consistent pressure to bring the foot into proper alignment. Correction of hyper pronation, or "flat feet," is another function of orthotics. The relief of excessive pronation can relieve other conditions such as shin splints or kneecap problems.

[0004] Two categories of orthotics are commonly available: (1) ready-made orthotics; and (2) custom molded or custom fit orthotics. Ready-made orthotics typically come in standard sizes and are relatively inexpensive. One problem with ready-made orthotics is that they often fit poorly or are uncomfortable because they do not accommodate the unique shape and size of each patient's foot. Custom molded orthotics are intended to solve this problem. Custom fit orthotics
are custom made to fit a particular foot size and shape, and thus they ought to fit comfortably on each patient. One problem with custom molded orthotics is that they often require the services of an expert to custom fit the orthotic, and they can be cost prohibitive due to the time and expertise required to custom make each orthotic.

[0005] Attempts have been made to provide custom molded orthotics that are custom fit by the user and less cost prohibitive than traditional custom molded orthotics. One such attempt utilizes a variety of chemicals in a liquid state placed inside an insole. First, the user initiates a chemical reaction in the chemicals within the insole. Next, the user places the insole inside a shoe, and wears the shoe as normally worn. The weight of the user on the insole molds the liquid chemicals inside the insole to conform to the shape of the user's foot. The chemical reaction occurring inside the insole causes the chemicals to transform from a liquid state to a solid state, resulting in a solid orthotic in the shape of the user's foot. Although such a custom molded orthotic is less cost prohibitive and does not require an expert to mold the orthotic, the problem with such molded orthotics is that the user cannot adjust the level of support of the orthotic.

[0006] The amount of chemicals in the insole determines the size and level of support of the orthotic, thus the orthotic will not give the desired level of support unless it initially contains the correct amount of liquid chemicals. The desired level of support may not be known by the user until the chemicals in the orthotic have set and the user feels the level of support given by the orthotic. However, once the chemicals have set, the level of support cannot be adjusted. Thus, the orthotic will conform to the user's foot but often does not provide the level of support desired.

[0007] Another attempt to provide custom fit orthotics that are custom fit by the user and less cost prohibitive than traditional custom molded orthotics utilizes a bladder filled with air. An air bladder is placed inside an insole, which is placed inside the user's shoe. Some embodiments require the user to use a pump to inflate the bladder before the shoe is placed on the user's foot. Other embodiments incorporate a pump inside the insole or shoe. The weight of the user works the pump, which inflates the bladder as the user walks while wearing the shoe. The inflated bladder is intended to conform to the shape of the user's foot as weight is placed on the user's foot.

[0008] Although some of such conventional custom fit orthotics allow the user to adjust the level of support of the orthotic, these custom fit orthotics may be complex to manufacture, involving complex pumps to inflate the bladder. The complex design and numerous parts required to inflate the bladder can be cost prohibitive. Further, the inflated bladder does not retain the shape of the user's foot when weight is removed from the foot.
The bladder is filled in these conventional devices with a fluid, in this case a gas, that freely shifts and flows inside the bladder as the weight on the user's foot shifts, thus causing the inflated bladder to change shape. Such a shifting of shape during different stages of walking may result in undesired changing levels of support.

What is needed is a custom fit support that conforms to shape of the user's anatomy, retains the shape of the user's anatomy, is efficient to manufacture, is relatively inexpensive, and has an adjustable level of support.

**BRIEF SUMMARY OF THE INVENTION**

The present invention therefore provides for a device for providing self-adjustable support for a user's foot. The device may comprise an insole member, an inflatable bladder arranged on the insole member and configured to generally conform to a portion of the user's foot, an open cellular foam material arranged in an interior of the inflatable bladder, a valve for controlling passage of air into and from the open cellular foam material contained in the interior of the inflatable bladder, and a stiffener member arranged beneath the insole member in an area of the inflatable bladder.

The open cellular foam material may substantially fills the interior. The inflatable bladder may be formed by an upper layer of the insole member and the stiffener member.

The insole member may comprise a fabric layer arranged on an upper surface, and wherein the inflatable bladder is defined by the fabric layer and the stiffener member. The insole member may comprise a four-way stretch fabric laminated with a polyurethane film, wherein the inflatable bladder is defined by the four-way stretch fabric laminated with the polyurethane film and the stiffener member. The insole member may comprise waterblown PU foam covered by a layer of four-way stretch fabric laminated with a polyurethane film.

The stiffener member may comprise a one-piece bent and shaped rigid or semi-rigid polyurethane member. A semi-rigid or rigid member is one that is significantly less flexible than other portions of the insole device such as the foam insole member. Semi-rigid or rigid also means that the member does not easily change in thickness (and/or is not easily compressible) when placed in compression as occurs with the foam insole member. The stiffener member may comprise, for example, 55 mil P.T. 9800 polyurethane.

The valve may comprise an operable member which is normally closed so that when air is essentially completely expelled from the inflatable bladder the open cellular foam material is substantially compressed so as to create a partial vacuum within the inflatable bladder with the operable member in the normally closed position.

The device for providing self-adjustable arch support for a user's foot may be structured and arranged so that the inflatable bladder positioned under the arch of a user's foot...
while in a non-weight bearing position, said operable member being opened in response to
activation by the user so that the inflatable bladder becomes self-inflating with the partial
vacuum drawing air into the interior of the inflatable bladder and causing said open cellular
material to expand and conform to the user's arch, whereby as the operable member is permitted
to return to the normally closed position, the open cellular material retains a shape, during
walking, that conforms to the user's arch as defined by the non-weight bearing position.

[0017] The valve may comprises one of: a finger-activated valve, a button valve, a
central stem valve, a duck-bill valve, an umbrella valve, a ball valve, a valve adapted to be
coupled to a tension member that can be activated by placing the tension member in tension, and
a multiple activation valve. The valve may be arranged on a angled side portion of the stiffener
member.

[0018] The open cellular foam material may comprise medium-density polyurethane
open cell foam. The open cellular foam material may comprise four pound density foam. The
open cellular foam material may comprise at least one of open cell foamed polyester, open cell
foamed polyether, and combinations thereof. The open cellular foam material may comprise at
least one of open cell glassy carbon foam, a combination of open cell foam and semi-closed
foam, a combination of open cell foam and closed cell foam, a composite that includes open cell
metal foam, and combinations thereof. The open cellular material may retain a shape that
conforms to the user's arch as defined by a non-weight bearing position during movement of the
foot. The open cellular material may retain a shape that conforms to the user's arch as defined by
a non-weight bearing position when a compressive force is provided by the foot. The open
cellular material may retain a shape that conforms to the user's arch as defined by a non-weight
bearing position when weight is applied to the foot. The open cellular material may retain a
shape that conforms to the user's arch as defined by a non-weight bearing position regardless of a
shifting weight applied on the foot.

[0019] The device for providing self-adjustable arch support for a user's foot wherein the
inflatable bladder is positioned substantially exclusively under the arch. The inflatable bladder,
prior to inflation, may have a volume which is less than a space under the arch of the foot.

[0020] The invention also provides for a method of making a device for providing self-
adjustable support, wherein the method comprises forming an inflatable bladder on a support
member, the inflatable bladder being defined by a material layer of the support member and a
stiffener member and comprising an open cellular foam material arranged in an interior of the
inflatable bladder and mounting a valve to a wall of the inflatable bladder.

[0021] The support member can be a sole member and the device can provide arch-
support for a user's foot. The inflatable bladder may be formed on the insole member in an area
of an arch of a foot. The forming may comprise molding a compressible material to the material layer in a mold to form a first sub-assembly, attaching the valve to a portion of the stiffener member to form a second sub-assembly, and connecting together the first and second sub-assemblies with the open cellular foam material arranged therebetween.

[0022] The method may further comprise, after the connecting, trimming the material layer to a predetermined shape.

[0023] The method may further comprise, before the connecting, shaping the open cellular foam material to a predetermined shape.

[0024] The method may further comprise, before or during the connecting, compressing the open cellular foam material between the stiffener member and the material layer.

[0025] The method may further comprise, before the molding, arranging the material layer in the mold.

[0026] The compressible material may comprise a waterblown PU foam.

[0027] The method may further comprise, before the connecting, shaping the stiffener member.

[0028] The portion of the stiffener member may comprise a bent side wall portion of the stiffener member. The stiffener member may comprise a one-piece bent and shaped rigid or semi-rigid polyurethane member. The stiffener member may comprise 55 mil P.T. 9800 polyurethane.

[0029] The connecting may comprise welding a perimeter area of the stiffener member to the material layer to form the inflatable bladder. The connecting may comprise RF welding a perimeter area of the stiffener member to the material layer to form the inflatable bladder.

[0030] The material layer may comprise a fabric layer covered layer. The material layer may comprise a layer of four-way stretch fabric laminated with a polyurethane film. The compressible material may comprise waterblown PU foam.

[0031] The valve may comprise one of: a finger-activated valve; a button valve; a central stem valve; a duck-bill valve; an umbrella valve; a ball valve; a valve adapted to be coupled to a tension member that can be activated by placing the tension member in tension; and a multiple activation valve.

[0032] The open cellular foam material may comprise medium-density polyurethane open cell foam. The open cellular foam material may comprise four pound density foam.

[0033] The device made by the method may be one of: a shoe insert; a pillow; an arm rest; a back rest; and an orthopedic brace.

[0034] The invention also provides for a device for providing self-adjustable arch support for a user's foot, wherein the device comprises a support member, an inflatable bladder arranged
on the support member and configured to generally conform to fit under an arch of a foot, the inflatable bladder having a wall formed by a stiffener member, a mechanism for inflating the inflatable bladder, and a valve for controlling passage of air into and from the mechanism for inflating the inflatable bladder.

[0035] These and other objects and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIG. 1 illustrates a top view of one non-limiting embodiment (left foot) of a custom conformable device for use as a custom fit orthotic in accordance with the invention;

FIG. 2 illustrates a bottom view of FIG. 1;

FIG. 3 illustrates a left-side view of FIG. 1;

FIG. 4 illustrates a right-side view of FIG. 1;

FIG. 5 illustrates a top view of a material sheet blank which will be used to form the upper layer of two devices of the type shown in FIG. 1;

FIG. 6 illustrates a front side view of the material blank shown in FIG. 5;

FIG. 7 illustrates a left side view of molded material shown in FIG. 8 which will be formed in a mold and become attached to the sheet material shown in FIG. 5 during molding.

FIG. 8 illustrates a top view of molded material shown in FIG. 7;

FIG. 9 illustrates a cross-section view of a portion of a two-piece mold which can be used to mold the sole member shown in FIG. 8;

FIG. 10 illustrates a partial cross-section view of the mold of FIG. 9 in the closed position and after the material which will form the sole member shown in FIG. 8 is poured into the female mold and solidified;

FIG. 11 illustrates a cross-section view of the molded left and right side sole members removed from the mold and with the mechanically attached sheet material;

FIG. 12 illustrates a top view of a stiffener member which have been cut to shape and punctured with an opening for a valve;

FIG. 13 illustrates a cross-section view of FIG. 12;
FIG. 14 illustrates a bottom view of the stiffener member shown in FIG. 12 after it has been bent along the arc-shaped bend-line and after the valve is secured thereto. The stiffener can then be attached to a left-foot device;

FIG. 15 illustrates a cross-section view of FIG. 14 but with the valve not shown in cross-section;

FIG. 16 illustrates a bottom view of the foam insert member which will be positioned in the arch-support bladder of the device shown in FIG. 1;

FIG. 17 illustrates a cross-section view of FIG. 16;

FIG. 18 illustrates a bottom view of the molded left and right side sole members mechanically attached sheet material and after the stiffener members have been secured to the upper material layer shown in FIG. 5; and

FIG. 19 illustrates a top view of FIG. 15.

DETAILED DESCRIPTION OF THE INVENTION

[0037] The present invention relates to custom conformable devices with a self-inflating bladder that conforms to the shape of a user's anatomy. The present invention also relates to a method making such custom conformable devices. The method may also be used to make, by way of non-limiting examples, a plurality of embodiments of custom conformable devices, such as a pillow-like head support to be used while either sitting in a seat or lying down; a back support to be placed behind the back of a user sitting in a seat; an arch support to be placed inside the shoe of a user; a support for a patient undergoing a surgical procedure; and a brace to be applied to an extremity. The present invention is an improvement over Applicant's issued US patent No. 6,782,640 to WESTIN, the disclosure of which is hereby expressly incorporated by reference in its entirety, and also provides for a method of making the improved device.

[0038] Illustrated in FIGS. 1-4 is one embodiment of a custom conformable device 1 incorporating features of the present invention. The custom conformable device 1 comprises an insole or insole member 2 and an inflatable bladder 3. Insole 2 is shaped such that when placed in a shoe, insole 2 substantially retains the position of inflatable bladder 3 under the arch of the user's foot (not shown). In this regard, the overall length AL of the bladder portion of the device 1 (see FIG. 2) can be sized for different types of users. Similarly, the device 1 can have an overall length OL (see FIG. 3) which can be standardized as, e.g., small, medium, large, etc., for use by different users.

[0039] The embodiments shown in the accompanying drawings illustrate by way of example a valve, such as valve 4, that opens to the atmosphere and regulates the passage of air flow. As will be described in detail below, the bladder 3 is formed by upper fabric layer UML.
(see FIGS. 5 and 6) and a stiffener member 7 (see FIGS. 14 and 15) and the insole member 2 is formed by upper fabric layer UML (see FIGS. 5 and 6) and a molded member 6 (see FIGS. 7 and 8). In the toe area of the device 1, the thickness "th" (see FIG. 4) of the insole member 2, which is made up of attached portions of upper layer UML and molded member 6, is significantly thinner than a heel area of the device 1 which is similarly made of attached portions of upper layer UML and molded member 6. Thickness th can be e.g., 0.05 inches and the thickness of the heel portion of the insole can be e.g., 0.170 inches.

[0040] Gas flow is a preferred fluid flow, and air flow is a more preferred fluid flow in embodiments of this invention. This fluid flow can be embodied by other fluids, including gases and liquids, taken into and expelled from the bladder in other embodiments of this invention. Air is expelled from the interior of bladder 3 by external compression of the bladder 3.

[0041] The illustrative embodiment shown in FIGS. 1-4 extends throughout the entire bottom surface of a foot, i.e., forming a complete insole. Other embodiments of the present invention extend only throughout part of the bottom surface of the foot, such as, for example, the surface below the arch and the toe area, or the arch of the foot and a central area of the foot, or the arch of the foot and a heel area of the foot, etc. Still other embodiments extend throughout part of some other region of the foot, such as the side and the top.

[0042] Inflatable bladder 3 utilizes the valve 4 and contains therein an expandable material 5 (see FIGS. 16 and 17). Valve 4 is located on or in the vicinity of bladder 3 such that valve 4 is easily accessible by the user of the custom conformable device 1. Valve 4 is preferably located on an underneath side of bladder 3 below the arch of the user's foot such that valve 4 does not cause discomfort to the user's foot. Valve 4 is configured to control the flow of air into and from the interior of inflatable bladder 3, and is preferably a finger-activated valve.

[0043] Embodiments of valves according to the present invention include finger-activated valves, button valves, umbrella valves, duck-bill valves, central stem valves such as Schraeder-type valves, ball valves, valves adapted to be coupled to a tension member that can be activated by placing the tension member in tension, and generally valves that perform like the valves typically found in bicycle and car tires. By way of non-limiting example, the valve 4 can be of the type made by Dielectrics Inc., of Chicopee Mass., and more specifically, can be Dielectrics' part number 73008 or 730006.

[0044] Mechanisms for controlling passage of gas into and from the bladder according to the present invention include finger-activated valves, button valves, umbrella valves, duck-bill valves, central stem valves such as Schraeder-type valves, and generally valves that are actuated by external pressure and then perform like the valves typically found in bicycle and car tires,
such that the fluid flow into the bladder and through the valve is drawn by expandable material within the bladder that expands from a compressed state to a more expanded state.

[0045] As described herein, embodiments of valve 4 and/or mechanisms for controlling passage of a gas into and from the bladder 3 according to the present invention are preferably configured in such a way that they can be repeatedly activated, so that the operations of allowing gas to flow into and/or to flow from the interior of the bladder 3 can be repeated many times at the user’s choice. This characteristic is referred to herein as "multiple activation". To facilitate multiple activation, embodiments of valve 4 and a mechanism for controlling passage of a gas into and from the bladder 3 according to this invention are preferably partially exposed, so that they can be reached easily.

[0046] In addition to embodiments with one valve 4 or with one mechanism for controlling passage of a gas into and from the bladder 3, the invention envisages embodiments with a plurality of valves or with a plurality of mechanisms for controlling the passage of gas into and from the bladder 3. For example, embodiments according to the present invention can be provided with, e.g., two valves. One of the valves in these embodiments can be chosen for quick deflation, whereas the other valve can be a low fluid flow valve for a more controlled regulation of the degree of inflation of the custom conformable device. Analogous considerations apply to embodiments with, for example, two mechanisms for controlling passage of a gas into and from the bladder 3.

[0047] Expandable material 5 within bladder 3 is compressible, capable of assuming a compressed and an expanded form, and can be an open cell foam, or more preferably medium-density polyurethane open cell foam, and most preferably four-pound polyurethane open cell foam. Although not shown, at least part of expandable material 5 can be embodied by particulate material in some embodiments. The particulate material can be loose and contained within the bladder 3 in some of the embodiments with particulate material. Expandable material 5 substantially fills the interior of bladder 3 in preferred embodiments of the present invention. Expandable material 5 can also partially fill the interior of bladder 3 in other embodiments of the present invention.

[0048] The term "expandable material" as used herein is an expandable material medium that is capable of expanding and contracting throughout at least a portion of such material medium, and such that fluid is drawn into the medium when expanding. This feature distinguishes expandable material as used herein from a container such as a hollow shell, balloon or empty vessel that could expand upon inflation and contract upon deflation, but that would not experience expansion and contraction throughout at least a substantial portion thereof because such shell, balloon or vessel provides no medium therein. The expansion and contraction is
experienced in these hollow containers only by the container walls, as opposed to the expansion and contraction of a material medium throughout the expandable material of the present invention. Furthermore, these hollow containers cannot retain a particular shape when they are partially or completely inflated; compared to that of the present invention.

[0049] The expandable material according to the present invention comprises solid material throughout the expandable material itself. This material provides a supportive element that does not shift throughout the interior of a container when the expandable material is contained therein and pressure externally applied to such container changes. A foam is an illustrative example of an expandable material.

[0050] The expandable material according to the present invention provides itself a material medium that does not shift as would a fluid when it is within a container subjected to changing external pressure. The property of "not shifting as a fluid" as used herein indicates that the substance to which it is applied does not flow when it is within a container that is subjected to changing external pressure. Furthermore, the expandable material according to the present invention provides a material medium that draws fluid throughout at least a portion of such material medium itself. These properties distinguish the expandable material of the present invention from an hollow container with only fluid therein, where the fluid can shift within the container as external pressure changes. These properties also distinguish the expandable material of the present invention from a container that only has in its interior fluid in combination with a material that does not absorb fluid itself.

[0051] Before use, valve 4 is opened and inflatable bladder 3 and expandable material 5 are compressed, with inflatable bladder 3 substantially deflated so that conformable device 1, and more specifically the bladder area, is substantially flattened. Valve 4 is then closed (with the preferred valve this occurs automatically when it is not in use) and the external compressive pressure is released or at least decreased, thus creating a degree of rarefaction inside inflatable bladder 3 when expandable material 5 tends to expand upon the release or diminution of the external pressure. This degree of rarefaction in the inflated device with respect to the surrounding environment is concisely referred to for simplicity as a vacuum. With valve 4 closed, expandable material 5 is prevented from expanding to a large extent.

[0052] Inflatable bladder 3 of the device 1 thus retains a substantially flattened form until valve 4 is opened and expandable material 5 is allowed to expand, thus drawing air into and inflating inflatable bladder 3. Valve 4 is closed when inflatable bladder 3 has inflated to a desired extent, and expandable material 5 further expands to some extent, which is termed as undergoing an incremental expansion, with valve 4 closed. This incremental expansion creates a vacuum within the inflated bladder 3 that contributes to the retention by the bladder 3 to the shape of the
body part to which it is applied, i.e., the arch of the foot. Filled and hollow containers that provide cushioning effect upon their complete inflation are devoid of this property.

[0053] As is apparent from FIGS. 1-4, the custom conformable device 1 can be placed into a shoe (not shown), and the shoe can be placed on a foot of a user. Custom conformable device 1 is preferably placed into a shoe in a substantially deflated and flat form. If custom conformable device 1 is inflated when it is placed into the shoe, the user can deflate it by opening valve 4 and pressing with the foot against the ground. The natural shape of the foot creates an arch space between custom conformable device 1 and the foot. Inflatable bladder 3 is configured such that when fully inflated, inflatable bladder 3 fills this arch space in the unweighted foot. Before weight is placed on the foot, for example, when the user is sitting or shifting all or at least a significant portion of the body weight to the other foot, a finger (not shown), is then inserted into the shoe to open valve 4. This can occur in a manner similar to that shown in FIG. 2 of US Patent No. 6,782,640 to WESTIN. This operation allows the flow of air into bladder 3 as expandable material 5 expands. This flow of air is controlled by the operation of valve 4 by the user.

[0054] Some embodiments of the present invention are configured so that an extension member, e.g., a strap (e.g., a flexible strap) or a tension member (e.g., a string) may be coupled to a valve such as valve 4 is used to open and close the valve without having to insert a finger through the space between the foot and the shoe all the way down to reach the valve itself. This would allow a user to activate the valve from an upper edge or rim area of the upper. This can be useful when the device is used inside of e.g., a boot, which may not provide sufficient space to allow the user to position her hand down to the area of the sole. By way of illustration but not as a limitation, an example of such extension member is the extension provided in various duck-tail bill valves to actuate the valve and regulate the fluid flow therethrough.

[0055] As inflatable bladder 3 inflates, inflatable bladder 3 fills arch space and conforms to the shape of the foot, i.e., in a manner similar to that shown in FIG. 3 of US Patent No. 6,782,640 to WESTIN. When inflatable bladder 3 has inflated to the desired level, the user closes valve 4, or more preferably allows the valve 4 to close automatically. Once valve 4 is closed, the user may apply weight to the foot and wear the shoe normally. Inflated bladder 3 supports and cushions arch area of the foot while the insole member 2 supports and cushions the toe and heel areas of foot as the user walks or runs. Expandable material 5 retains inflated bladder 3 in conformation to the shape of the foot regardless of how the weight of the user shifts on foot during walking or movement.

[0056] Depending on the composition of specific embodiments of the expandable material 5, changes in pressure applied to the expandable material while in use will cause slight
variations in its shape according to its firmness and springiness. Terms such as "substantially retains the shape of the user's anatomical part" are used herein to refer to these variations. Similarly, the adverb "substantially" is applied herein to qualify terms related to the bladder because of variations in the anatomical part, e.g., the arch of the foot, to which it is applied and variations derived from the physical properties of the bladder material itself. Inflation and deflation operations such as those described hereinabove can be performed as many times as desired by the user of embodiments of the present invention. Expandable material 5 retains the shape of bladder 3 regardless of the shifting weight on foot during walking or other movement by the user.

The term "shoe" is used herein to describe a foot-borne item on at least a part of which the foot rests, and such that this item moves together with the foot when walking or displacing the foot. This term as used herein comprises, but is not limited to, different types of shoes, such as athletic shoes, dress shoes, slippers, boots, casual shoes, sandals, shoes that are configured for use in conjunction with another device, such as skates and skis, and orthopedic shoes.

FIGS. 1-4 illustrate by way of example an embodiment of the present invention which can be inserted below the bottom of a foot. Embodiments of the present invention are also configured for their insertion between some other anatomical region and an item that allows for the implementation of operations such as the following: inflation and deflation of the bladder 3, compression and expansion of the expandable material 5 by controlled application of external pressure, and fluid flow regulation from and into the interior of the bladder 3. For example, embodiments of custom conformable devices 1 according to this invention can be placed between an interior area of a shoe, such as a ski boot, a hiking boot and a running shoe, and a specific region of the foot that is to be cushioned and/or supported when the user wears such ski boot, hiking boot or running shoe.

FIGS. 5-19 illustrate one non-limiting way in which the device 1 can be made according to the present invention. The method begins by cutting a section, e.g., a rectangular or square-shaped section of the material which will form the upper surface or upper material layer UML of the insole device 1. As is shown in FIG. 5, the section UML is preferably sized to allow for the making on two insole devices 1 (whose outline are shown in dashed-lines) at a time, i.e., both the left side and right insole devices 1. The section UML is cut from a roll of sheet material (see FIG. 6) and is preferably a fabric layer, and most preferably, a layer of four-way stretch fabric laminated with a polyurethane film.

Next, a synthetic resin cushioning support member 6 having the configuration/shape shown in FIGS. 7 and 8 and an arch opening AO is formed and attached to
the section UML. With reference to FIG. 9, it can be seen that this step takes place in a mold M, and more specifically a two-piece heated mold. In FIG. 9, the mold is shown in the open position with the material sheet shown in FIG. 5 arranged between the upper male mold and the lower female mold. The step begins by a user placing the section UML into the open mold M with the fabric layer facing upwards, i.e., facing the male or upper mold half M1 and with the polyurethane film layer facing downwards, i.e., facing the female or lower mold half M2. Preferably, the section UML is temporarily secured to the upper mold half M1 via pins (not shown) arranged on the upper mold half M1. The user then pours into the cavities of the lower mold half M2 a predetermined amount of liquid compressible material, and more preferably a waterblown PU (polyurethane) foam. The foam can be e.g., a milliken reacting red X-64 material. The mold M is then closed for a period of time until the waterblown PU foam solidifies (see FIG. 10). During solidification, the molded sole member shown in FIG. 8 becomes mechanically attached to the sheet material shown in FIG. 5. This step results in the formation of two of the molded member(s) shown in FIGS. 7 and 8 and their mechanical attachment to the section UML. The molded sub-assembly is then removed from the mold M and emerges with the configuration shown in FIG. 11.

[0061] Next, a synthetic resin stiffener or stiffener member or stiffener support member 7 having the configuration/shape shown in FIGS. 12 and 13 is formed. The member 7 is preferably punch cut from a sheet of 55 mil P.T. 9800 polyurethane. This shaping step preferably simultaneously forms both the outer shape of member 7 and the valve opening VO.

[0062] The synthetic resin stiffener support member 7 is then deformed or bent, i.e., along bend line or zone BL, to the shape shown in FIGS. 14 and 15. The valve 4 is also secured and/or fixed to the stiffener 7, preferably by RF welding the flange of the valve 4 to the upper surface of the stiffener member 7 in an area of the opening VO. As is shown in FIG. 2, this would form a weld zone WS2. RF welding is well known, as is evidenced by the following US Patent Nos; US 5,645,671 to TILLINGHAST, US 6,945,944 to KUIPER et al, and US 7,172,566 to WEAVER, II et al., the entire disclosures of each of these documents is hereby expressly incorporated by reference in their entireties. The deforming of the stiffener 7 to the shape shown in FIGS. 16 and 17, and the RF welding of the valve 4 thereto, preferably takes place in a single station or step. This step can take place in a fixture of the RF welding device (not shown). The stiffener/valve sub-assembly is then removed from the RF welding device and emerges with the configuration shown in FIGS. 14 and 15. A right-foot stiffener would have a configuration that is the mirror-image of that shown in FIG. 14.

[0063] Next, a compressible member 5 having the configuration/shape shown in FIGS. 16 and 17 is formed. The member 5 is preferably punch cut from a sheet of open cellular foam.
material, or preferably medium-density polyurethane open cell foam, and most preferably four pound density polyurethane open cell foam.

[0064] Next, the stiffener support member 7 (i.e., one for each of the left and right insole devices) is secured to the bottom surface of the section UML within the arch opening AO (see FIG. 6) of the molded member 6. Prior to the stiffener member 7 being secured to the upper material layer UML, the foam material member(s) 5 shown in FIG. 16 are placed therebetween and are compressed by the securing of the stiffener member(s) 7 to the upper layer material sheet UML. However, before this securing step can take place, the user properly positions the foam member 5 in the arch opening AO and then positions the stiffener member 7 over the foam member 5. The stiffener 7 is secured and/or fixed to the material UML preferably by RF welding a perimeter area of the stiffener 7 to lower surface of the material UML within a perimeter area of the arch opening AO.

[0065] As is shown in FIG. 18, this securing step produces a welding zone WSI which extends completely around the stiffener 7 and, together with the material UML, forms the inflatable bladder 3. Thus, as is evident from FIGS. 18 and 19, the inflatable bladder 3 is defined by the stiffener 7 and the upper material UML. That is, the material UML forms the upper wall of the bladder 3 and the stiffener 7 forms the lower wall of the bladder 3. Once the material UML is trimmed to the overall desired shape of the device 1, it will function both as the entire upper layer 2 of the device 1 and the upper wall of the bladder 3.

[0066] Of course, the invention contemplates other ways of securing the valve 4 to the stiffener 7 and other ways of securing the stiffener 7 to the upper material UML, such as ultrasonic welding, adhesive attachment, etc., provided it results in bladder 3 which is air tight and capable of repeated inflation and deflation and the stresses that accompany such conditions.

[0067] Embodiments of expandable material which will form foam member 5 according to the present invention also include open cell foam, open cell foamed polyester, open cell foamed polyether, open cell polyurethane, open cell glassy carbon foam, combinations of open cell foam and a material, such as semi-closed cell and closed cell foam, for added resilience. Open cell foam, such as medium density polyurethane open cell foam, is a preferred embodiment of expandable material. Further embodiments of expandable material according to the present invention comprise a composite of a foam and open cell metal foams, which have the additional advantages of a resilient component and a heat-dissipating component, and combinations of the foregoing embodiments of expandable material. Various embodiments of expandable material according to the present invention include materials such as those described herein, including these materials in mechanically shaped foam, in particulate form, thermo-formed, and combinations thereof.

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Mechanisms for inflating a bladder according to the present invention include open cell foam, open cell foamed polyester, open cell foamed polyether, open cell polyurethane, open cell glassy carbon foam, combinations of open cell foam and a material, such as semi-closed cell and closed cell foam, for added resiliency, and combinations of the foregoing embodiments of mechanisms for self-inflating a bladder. Open cell foam, such as medium density polyurethane open cell foam, is a preferred embodiment of a mechanism for inflating a bladder.

Further embodiments of the mechanisms for inflating a bladder according to the present invention comprise a composite of a foam and open cell metal foams, which have the additional advantages of a resilient component and a heat-dissipating component, combinations of the foregoing embodiments of mechanisms for inflating a bladder. Additional embodiments of mechanisms for inflating a bladder according to the present invention generally include open-cell-comprising materials that perform with respect to compression and expansion in a manner similar to the foregoing examples of mechanisms for inflating a bladder.

Embodiments of mechanisms for inflating a bladder according to the present invention can further also include a material medium that does not shift as a fluid when it is within a container subjected to changing external pressure. Furthermore, embodiments of mechanisms for inflating a bladder according to the present invention provide a material medium that draws fluid throughout at least a portion of such material medium itself.

The embodiments of mechanisms for inflating a bladder according to the present invention can also include materials such as those described herein, including these materials in mechanically shaped form, in particulate form, thermo-formed, and combinations thereof.

Mechanisms for substantially retaining the shape of a bladder according to the present invention can include open cell foam, open cell foamed polyester, open cell foamed polyether, open cell polyurethane, open cell glassy carbon foam, combinations of open cell foam and a material, such as semi-closed cell and closed cell foam, for added resiliency, and combinations of the foregoing embodiments of mechanisms for substantially retaining the shape of a bladder. Open cell foam, such as medium density polyurethane open cell foam, is a preferred embodiment of mechanisms for substantially retaining the shape of a bladder.

Further embodiments of mechanisms for substantially retaining the shape of a bladder according to the present invention comprise a composite of a foam and open cell metal foams, which have the additional advantages of a resilient component and a heat-dissipating component, combinations of the foregoing embodiments of mechanisms for self-inflating a bladder. Additional embodiments of mechanisms for substantially retaining the shape of a bladder according to the present invention generally include open-cell-comprising materials that...
perform with respect to shape retention in a manner similar to the foregoing examples of mechanisms for substantially retaining the shape of a bladder.

[0074] Embodiments of mechanisms for substantially retaining the shape of a bladder according to the present invention provide a material medium that does not shift as a fluid when it is within a container subjected to changing external pressure. Furthermore, embodiments of mechanisms for substantially retaining the shape of a bladder according to the present invention provide a material medium that draws fluid throughout at least a portion of such material medium itself.

[0075] Still further, embodiments of mechanisms for substantially retaining the shape of a bladder according to the present invention include materials such as those described herein, including these materials in mechanically shaped form, in particulate form, thermoformed, and combinations thereof.

[0076] The mechanisms for substantially retaining the shape of a bladder and the mechanisms for inflating a bladder can be embodied by the same material in some embodiments of the present invention, whereas they are embodied by different materials in other embodiments of the present invention.

[0077] Different embodiments of the bladder wall material according to the present invention can include materials such as vinyl; polyurethane; materials, including composites, with flexible fabrics such as neoprene coating material; elastic film materials; composites with flexible fabrics of natural and manufactured fibers; and combinations of such materials.

[0078] The closed cell materials in structures of composites with closed cell materials can comprise and/or resemble, in embodiments of the present invention, a cellulose sponge, with all or at least most of the cells separated from one another by walls. The structures of open cell materials comprised in embodiments of the present invention resemble a loofah sponge, with holes of varying size. The preferred hole size range of open cell materials being such that the expandable material effectively draws fluid into its interior and thus into the interior of its surrounding bladder through the open valve when the expandable material expands from a compressed state.

[0079] The expandable material can also be loose while contained within the bladder in some embodiments of the present invention. The bladder can be embodied by a shell that is integrally formed around the outer surface of the expandable material in other embodiments of the present invention. In other embodiments of the present invention, a supportive core of open cell foam is bonded between two layers of closed cell foam that enclose the open cell foam core in fluid-leak-proof containment and the bonded material has a valve to control fluid flow therethrough.
The expandable material or the bladder can also comprise a plurality of laminated materials in other embodiments of the present invention. The expandable material and the bladder can comprise a plurality of laminated materials in still other embodiments of the present invention.

A preferred embodiment of the present invention includes an insole that substantially retains the bladder in a selected position, such as below the arch of the foot of the user when the insole is placed in a shoe and worn by the user. The insole is preferably attached to the bladder in this embodiment.

Illustrative pillows as custom conformable devices made according to the present invention are embodied by head pillows, neck pillows, back pillows, cushions that can be removably attached to various parts of the human body, and surgery pillows that are used to provide custom fit support during medical intervention into a patient's body, including anesthesia for surgical procedures.

Illustrative arm rests as custom conformable devices made according to the present invention are embodied by cushions that provide custom fit support when in contact with any one of the various parts of a user's arm. Arm rests according to the present invention include embodiments for use with the arm merely resting on the arm rest, and embodiments for use with the arm rest removably attached to the arm, such as by strapping the arm rest to the arm.

Illustrative back rests as custom conformable devices made according to the present invention are embodied by cushions that provide custom fit support to any one of various regions of a user's back when the cushion is placed between the user's back and a surface against which pressure is exerted. The cushion is detached from such surface in some of these embodiments, whereas the cushion is attached to such surface in other embodiments.

Illustrative orthopedic braces as custom conformable devices made according to the present invention are embodied by cushions that are placed by a region of the anatomy of the user, such as a lower extremity region, and a brace framework, and by braces which have a cushion according to the present invention attached to or as an integral part of the brace.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.
WHAT IS CLAIMED:

1. A device for providing self-adjustable support for a user's foot, the device comprising:
   an insole member;
   an inflatable bladder arranged on the insole member and configured to generally conform to a portion of the user's foot;
   an open cellular foam material arranged in an interior of the inflatable bladder;
   a valve for controlling passage of air into and from the open cellular foam material contained in an interior of the inflatable bladder; and
   a stiffener member arranged beneath the insole member in an area of the inflatable bladder.

2. The device of claim 1, wherein the open cellular foam material substantially fills the interior.

3. The device of claim 1, wherein the inflatable bladder is formed by an upper layer of the insole member and the stiffener member.

4. The device of claim 1, wherein the insole member comprises a fabric layer arranged on an upper surface, and wherein the inflatable bladder is defined by the fabric layer and the stiffener member.

5. The device of claim 1, wherein the insole member comprises a four-way stretch fabric laminated with a polyurethane film, wherein the inflatable bladder is defined by the four-way stretch fabric laminated with the polyurethane film and the stiffener member.

6. The device of claim 1, wherein the insole member comprises waterblown polyurethane (PU) foam covered by a layer of four-way stretch fabric laminated with a polyurethane film.

7. The device of claim 1, wherein the stiffener member comprises a one-piece bent and shaped rigid or semi-rigid polyurethane member.

8. The device of claim 1, wherein the stiffener member comprises 55 mil P.T. 9800 polyurethane.

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9. The device of claim 1, wherein the valve comprises an operable member which is normally closed so that when air is essentially completely expelled from the inflatable bladder the open cellular foam material is substantially compressed so as to create a partial vacuum within the inflatable bladder with the operable member in the normally closed position.

10. The device of claim 9, wherein the device is structured and arranged so that the inflatable bladder is positioned under an arch of a user's foot while in a non-weight bearing position, the operable member being opened in response to activation by the user so that the inflatable bladder becomes self-inflating with the partial vacuum drawing air into the interior of the inflatable bladder and causing the open cellular material to expand and conform to the user's arch, whereby as the operable member is permitted to return to the normally closed position, the open cellular material retains a shape, during walking, that conforms to the user's arch as defined by the non-weight bearing position.

11. The device of claim 1, wherein the valve comprises one of:
   a finger-activated valve;
   a button valve;
   a central stem valve;
   a valve adapted to be coupled to a tension member that can be activated by placing the tension member in tension;
   a duck-bill valve;
   an umbrella valve; and
   a multiple activation valve.

12. The device of claim 1, wherein the open cellular foam material comprises medium-density polyurethane open cell foam.

13. The device of claim 1, wherein the open cellular foam material comprises four pound density foam.

14. The device of claim 1, wherein the open cellular foam material comprises at least one of open cell foamed polyester, open cell foamed polyether, and combinations thereof.

15. The device of claim 1, wherein the open cellular foam material comprises at least one of open cell glassy carbon foam, a combination of open cell foam and semi-closed foam.
combination of open cell foam and closed cell foam, a composite that includes open cell metal foam, and combinations thereof.

16. The device of claim 1, wherein the valve is arranged on an angled side portion of the stiffener member.

17. The device of claim 1, wherein the open cellular material retains a shape that conforms to the user's arch as defined by a non-weight bearing position during movement of the foot.

18. The device of claim 1, wherein the inflatable bladder is positionable substantially exclusively under the arch.

19. The device of claim 1, wherein the open cellular material retains a shape that conforms to the user's arch as defined by a non-weight bearing position when a compressive force is provided by the foot.

20. The device of claim 1, wherein the open cellular material retains a shape that conforms to the user's arch as defined by a non-weight bearing position regardless of a shifting weight applied on the foot.

21. The device of claim 1, wherein the inflatable bladder, prior to inflation, has a volume which is less than a space under an arch of the foot.

22. A method of making a device for providing self-adjustable support for a user, the method comprising:
   forming an inflatable bladder on a support member, the inflatable bladder being defined by a material layer of the support member and a stiffener member and comprising an open cellular foam material arranged in an interior of the inflatable bladder; and
   mounting a valve to a wall of the inflatable bladder.

23. The method of claim 22, wherein the device provides self-adjustable arch support for a user's foot and the inflatable bladder is formed on the insole member in an area of an arch of a foot.
24. The method of claim 22, wherein the forming comprises molding a compressible material to the material layer in a mold to form a first sub-assembly, wherein the mounting comprises attaching the valve to a portion of the stiffener member to form a second sub-assembly, and further comprising connecting together the first and second sub-assemblies with the open cellular foam material arranged therebetween.

25. The method of claim 24, further comprising, after the connecting, trimming the material layer to a predetermined shape.

26. The method of claim 24, further comprising, before the connecting, shaping the open cellular foam material to a predetermined shape.

27. The method of claim 24, further comprising, before or during the connecting, compressing the open cellular foam material between the stiffener member and the material layer.

28. The method of claim 24, further comprising, before the molding, arranging the material layer in the mold.

29. The method of claim 24, wherein the compressible material comprises a waterblown PU foam.

30. The method of claim 24, further comprising, before the connecting, shaping the stiffener member.

31. The method of claim 24, further comprising, before the connecting, shaping and bending the stiffener member so that stiffener member comprises a bent side wall portion.

32. The method of claim 24, wherein the connecting comprises welding a perimeter area of the stiffener member to the material layer to form the inflatable bladder.

33. The method of claim 24, wherein the connecting comprises RF welding a perimeter area of the stiffener member to the material layer to form the inflatable bladder.
34. The method of claim 22, wherein the material layer comprises a fabric layer covered layer.

35. The method of claim 22, wherein the material layer comprises a layer of four-way stretch fabric laminated with a polyurethane film.

36. The method of claim 22, wherein the compressible material comprises waterblown PU foam.

37. The method of claim 22, wherein the stiffener member comprises a one-piece bent and shaped rigid or semi-rigid polyurethane member.

38. The method of claim 22, wherein the stiffener member comprises 55 mil P.T. 9800 polyurethane.

39. The method of claim 22, wherein the valve comprises one of:
   a finger-activated valve;
   a button valve;
   a central stem valve;
   a valve adapted to be coupled to a tension member that can be activated by placing the tension member in tension;
   a duck-bill valve;
   an umbrella valve; and
   a multiple activation valve.

40. The method of claim 22, wherein the open cellular foam material comprises medium-density polyurethane open cell foam.

41. The method of claim 22, wherein the open cellular foam material comprises four pound density foam.

42. The method of claim 22, wherein the device is one of:
   a shoe insert;
   a pillow;
   an arm rest;
   a back rest; and
43. A device for providing self-adjustable arch support for a user's foot, the device comprising:
   a support member;
   an inflatable bladder arranged on the support member and configured to generally conform to fit under an arch of a foot, the inflatable bladder having a wall formed by a stiffener member;
   a mechanism for inflating the inflatable bladder; and
   a valve for controlling passage of air into and from the mechanism for inflating the inflatable bladder.
INTERNATIONAL SEARCH REPORT

A CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A43B 7/14 (2008.01)
USPC - 36/153

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 13/18, 13/20, 17/14, A64F 5/14, 5/32, 5/34 (2008.01)
USPC - 36/4 29, 43, 71, 88, 93, 154, 155, 126/882, 493

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
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<th>Category</th>
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<th>Relevant to claim No</th>
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<tr>
<td>X</td>
<td>US 2003/0046831 A1 (WESTIN) 13 March 2003 (13 03 2003) entire document</td>
<td>1-2, 5-6, 8-21, 43</td>
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