NEUROPATHIC FOOT PROTECTOR

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Publication Classification

Int. Cl. \( \text{A43B 7/14} \)
U.S. Cl. \( \text{36/27; 36/93; 36/154} \)

ABSTRACT

A shoe for treating and preventing chronic foot wounds such as ulcerations in diabetes patients. A malleable shoe upper is attached to a sole and receives a custom-fitted orthosis produced by imprinting the patient's plantar aspect into heat-deformable foam or a hardening silicone. A heel of the shoe includes an internal spring to further dampen reactive forces.
NEUROPATHIC FOOT PROTECTOR

FIELD OF THE INVENTION

[0001] The present invention relates to the field of protective foot gear and, in particular, a foot protector for preventing or treating foot ulcers in neuropathic patients.

BACKGROUND OF THE INVENTION

[0002] Tissue wounds are common injuries. Wounds can be internal or external. Discontinuity in the integrity of the skin is typically referred to as an external wound.

[0003] External wounds can be produced from external trauma, such as impact or cutting forces. Such external trauma may be deliberate, as in the case of an incision produced by a surgeon’s scalpel, or accidental, as in the case of scrapes and cuts produced by common accidents. A further category of external wounds includes chronic wounds produced in a predictable but to some extent unavoidable manner by chronic friction pressure and inflammation, e.g., diabetic foot ulcers, pressure ulcerations (bed sores) and venous insufficiency ulcerations.

[0004] The formation and healing of external chronic wounds is aggravated by vascular disease. Reductions in blood flow to a tissue site can itself produce a wound by resulting in insufficient tissue oxygenation or insufficient fluid drainage. Because vascular disease is typically chronic, the resultant wounds are also chronic.

[0005] Diabetes presents special wound complications and severity. Approximately 19 million people have diabetes in the United States alone, of whom a third are undiagnosed. Of the two-thirds who are diagnosed, 90% (about 9.9 million) have Type II diabetes and 10% (about 1.1 million) have Type I diabetes.

[0006] Diabetes patients often suffer from varying degrees of vascular disease and sensory peripheral neuropathy; in other words, their feet and hands tend to be insensitive. In more extreme cases, the patient has little or no sensation in his feet. When a wound develops in such a patient, the patient experiences no pain, and indeed may be wholly unaware of the wound. Many of these wounds are on pressure points on the foot. As the insensitive patient continues to apply pressure to these wound points, as by simply walking, the wound becomes very severe, ulcerated and perhaps infected. The repeated trauma of ambulation contributes to the wound formation at the outset. Vascular impairment further compromises the healing of these wounds. It has been estimated that there are 800,000 diabetic foot ulcer cases per year in the United States, representing 3.5 to 7% of the diagnosed diabetes population. The population at highest risk has sensory peripheral neuropathy, with or without peripheral vascular disease, foot deformities or a history of wounds.

[0007] When a foot ulcer becomes infected often the only option is amputation to save the patient’s life. These diabetic foot ulcers result in about 67,000 foot amputations per year in the United States alone. They account for more hospitalizations than any other single complication of diabetes. The problem appears to be worsening; the lower extremity amputation rate has increased each year since 1990. About 84% of these amputations are preceded by foot ulcers.

[0008] The significance of these cases can be measured both in quality of life and economic indicators. Quality of life issues are particularly important because nontraumatic ulceration can lead a patient with diabetes through a cycle of ulceration, subsequent infection, antibiotic treatment, hospitalization, and lower extremity amputation with long-term therapy. This sequence of events can produce long-term disability which burdens the family attempting to care for this individual.

[0009] The economic effect of these cases is staggering. American Diabetes Association statistics show that 16% of healthcare expenditures in the United States are spent on patients with diabetes, and that 10% of that money is spent directly related to foot conditions. National economic statistics show an average hospital length of stay of 19 days for infected diabetic ulcerations. It is believed that the cost of a lower extremity amputation averages a total of about $75,000 from the initial presentation of the wound to a resulting amputation. If that figure is accurate, then the annual cost of the 67,000 amputations in the United States alone is over $5 billion. Further, the treatment cost for the 800,000 foot ulcerations in diabetes patients, even without amputation, averages $5,000 per year, for a total of another $4 billion.

[0010] The Vascular Advisory Board to the American Diabetes Association has indicated that approximately one-third of the 67,000 annual amputations are unavoidable. This is mainly due to the inability of the patient to have a revascularization procedure performed. Compounding this, several studies have verified that contra lateral limb amputations occur in 30% to 60% of the patients who have undergone one lower extremity amputation. As daunting as these figures are, however, two-thirds of the 67,000 annual amputations are considered avoidable, or over 44,000.

[0011] It has been shown that well-constructed and properly fitting shoes are necessary to avoid foot wounds in diabetes patients, particularly in patients with sensory peripheral neuropathy and motor neuropathy. Fashion styles, especially for women, often influence selection of footwear instead of considerations of comfort and support. The purpose of the footwear from a medical standpoint must be to provide support, foot stability, shock absorption, and a foundation for orthoses.

[0012] Reimburseers such as Medicare acknowledge the need for preventing foot ulcers for high-risk patients with diabetes. Provisions currently allow for one pair of extra-depth, extra-width shoes and three pairs of orthoses per year to be provided to high-risk patients. Three pairs are allowed because “accommodative” orthoses are inherently flexible and compressible by nature. This allows for protection of potential ulcerative locations, but also means a limited lifespan of three to four months per pair.

[0013] The tragic personal consequence and horrendous economic implications of foot ulcers in diabetes patients has led to several prevention and treatment modalities. Six of these are briefly described below:

[0014] 1. Custom-made, custom-molded shoes with accommodative full-contact orthosis fabricated from a positive cast. Accommodative, for above-noted purposes, is defined as devices which attempt to support the foot without changing or altering biomechanical function. A shell requiring the use of recognized accepted protective materials
interfacing with the insensitive foot, such as PlastoZote or Poron brand materials, together with posting materials provide the rigidity of the rear foot orthosis. These shoes are the only medically indicated treatment for severely deformed feet, partial foot amputees (e.g., transmetatarsal amputation), severe foot deformity, (e.g., Charcot deformity with midfoot collapse), severe hammertoe deformities, and severe hallux valgus deformities. This alternative is appropriate for only 5% to 8% of patients that have foot structures mandating custom shoes and orthoses.

[0015] 2. Extra-depth, extra-width over-the-counter shoes with custom-molded tri-density accommodative full-contact orthosis fabricated from a positive cast. This is the same as the orthosis described in the preceding paragraph, but the shoes are over-the-counter and not custom-made. The advantages are: (1) improved appearance; (2) less expense; (3) more variety of styles; and (4) more ready availability. The limitations are that: (1) the shoe is not custom made; (2) it cannot fit severe deformities; and (3) it requires external shoe modifications at times, which are dependent upon personnel in the clinic.

[0016] This orthosis redistributes pressure throughout the entire foot, which decreases pressure in the high-risk areas to thereby reduce risk of ulceration. However, this orthosis is relatively expensive and time-consuming to construct, tends to be variable in its manufacture, is often poorly made, and the patient needs three pair per year.

[0017] This orthosis has been used in research at the Diabetic Foot and Wound Center in Denver, Colo. Over 450 ulcerations were healed and subsequently placed in extra-depth or extra-width shoes with custom-molded tri-density fabricated orthoses, fabricated from a positive cast. The result was a 24.9% recurrence rate. For purposes of this study, “recurrence” is defined as re-ulceration at the same site. Previous studies have shown an 86% recurrence rate if these techniques were not utilized. In general, this orthosis is recognized as the Gold Standard in preventing diabetic foot pressure ulcers and is appropriate for the high-risk patients with diabetes who do not qualify for alternative #1 above.

[0018] 3. Extra-depth shoes with accommodative non-full-contact fabricated inlay. A shoe manufacturer, such as Apex Ambulators, often provides this type of orthosis. These shoes are very inexpensive, and they can accommodate minor dorsal deformities such as hammertoes or first metatarsocuneiform exostoses. The disadvantage is that they are not clinically effective in reducing plantar surface pressures where 95% of the wounds occur. In essence, this is not an option for the high-risk diabetic foot as previously described. This is commonly the type of device that is dispensed by nationally known orthopedic providers charging $400 to $600 for shoes and inlays.

[0019] 4. Extra-depth shoes with nonaccommodative, non-full-contact inlays. This type of appliance is often provided by a shoe manufacturer such as New Balance and PW Minor companies. These shoes have the advantage of being inexpensive and they can be used with minor dorsal deformities. The disadvantages are that the inlays are not accommodative, nor are they full contact. Also patients can buy and fit themselves. This is not a good situation, as patients with diabetes traditionally fit the shoes too tight, due to the loss of foot sensation, and develop further complications.

[0020] 5. Non-extra-depth over-the-counter shoes. The only advantage of these kind of shoes is that there is increased selection, color, and style. These shoes (1) do not have the required depth currently mandated by the Medicare Therapeutic Shoe Bill to accommodate a three-eighths of an inch orthosis once the factory inlay is removed; (2) have a non-oblique toe box; (3) have a lack of medical and lateral rear foot stability; (4) will not accommodate dorsal deformities; and (5) will not accept an accommodative, prefabricated, or custom orthosis due to lack of depth of the shoe. These are commonly the type of shoes that patients with new ulcers are wearing when they first seek care for their foot problem. Medically this is not an acceptable option.

[0021] 6. Open-toe, open-heel shoe gear. The open toe offers the advantage of extra room for dorsal deformities. The main disadvantage is that this type of shoe exposes the foot to trauma by allowing outside entrance of foreign objects such as rocks, coins, pins, etc. In addition, this shoe has no accommodative plantar protection, and it allows excessive lateral shear forces.

SUMMARY OF THE INVENTION

[0022] A goal of the present invention is to prevent as many lower extremity amputations as possible by preventing the initial ulcer from occurring. This addresses a crucial need in the chain of events prior to amputation, protecting the high-risk foot before an ulcer occurs. The invention can be made readily available to patients without the limitations of time and money inherent in present alternatives.

[0023] The present invention is a one-unit protective shoe and custom-fitted orthosis system. The shoe, orthosis and foot function as one unit because ground reactive forces are addressed by the shoe and shearing forces are addressed by the orthosis. Current alternatives can only be piece-mealed together, thereby compromising the effectiveness of the intended purpose of wound prevention. This addresses the cost, time, and variability shortcomings of current alternatives. The ease of application and use of this invention can increase use, thus reducing the number of foot wounds, the number of lower extremity amputations, and healthcare costs.

[0024] Twenty percent of patients with diagnosed diabetes—a total of 2.2 million individuals—are deemed at high risk for developing neuropathic foot ulcers. The use of the present invention to avoid wounds would result in system-wide cost-savings by preventing many wounds entirely, thereby eliminating the cost of subsequent treatments such as hospitalization, surgical intervention, and rehabilitation. If using the present invention results in only a 5% (2,233) reduction of amputations deemed “avoidable” with proper intervention (4,660), there would be a $167,497,500.00 savings in healthcare spending (assuming an average cost of $75,000 per amputation). With diabetes accounting for 16% of the healthcare dollars in the USA, and foot-related complications representing 10% of the total cost of care for diabetes, this treatment modality would readily be embraced by governmental agencies and managed care organizations.

[0025] The present invention couples a customized protective orthosis with appropriate shoe gear. It has three main components:
[0026] 1) An orthosis that:
[0027] a. Protects bony prominences on the plantar foot,
[0028] b. Is custom and full-contact,
[0029] c. Maintains protection over extended period of time without compromise,
[0030] d. Is quick and easy to produce.

[0031] 2) A shoe that has the characteristics of being:
[0032] a. Extra-depth,
[0033] b. Extra-width,
[0034] c. Deep toe-box,
[0035] d. Negative heel,
[0036] e. Malleable to allow for stretching around bone prominences,
[0037] f. Comparable in weight to New Balance and PW Minor shoes,
[0038] g. Protective to bony prominence on the distal toes; dorsal, medial and lateral foot; and the Achilles tendon region posterior through appropriate materials and scam construction,
[0039] h. Shock absorbing heel.

[0040] 3) A means to merge the orthosis and shoe resulting in excellent protection of the insensitive foot.

[0041] This present invention includes shoe upper which is malleable to be conformed to irregularities in a patient’s foot. The shoe upper is attached to a sole which includes an integral heel spring in a foam surround. Fitted inside the shoe is the orthosis. The orthosis is designed to be custom molded to the patient’s foot, using a heat deformable closed foam material or a quick-setting silicone in a rubber bladder. The integrated unit allows shear forces to be minimized by the interface between the custom molded orthosis and the patient’s foot, and allows ambulation impact forces to be absorbed by the heel spring.

BRIEF DESCRIPTION OF THE DRAWINGS

[0042] FIG. 1 is an exploded view of the present invention, showing a shoe upper, an orthosis, a sole and a heel.

[0043] FIG. 2 shows the process of imprinting the planter aspect of a patient’s foot onto an orthosis in accordance with one preferred embodiment of the invention.

[0044] FIG. 3 shows the process of injecting silicone resin and curing agent into a bladder orthosis in accordance with another preferred embodiment of the invention.

[0045] FIG. 4 shows the invention with a cut-away section showing the inside of a heel.

DETAILED DESCRIPTION OF THE INVENTION

[0046] The invention comprises two main elements: an orthosis and a shoe. An external exploded view of a preferred embodiment of the invention 10 is shown in FIG. 1. The invention 10 includes a shoe upper 42 and orthosis 14, a sole 50, and a heel 48.

[0047] First described is the orthosis 12 which serves as a footbed inside the shoe. The purpose of the orthosis 12 is to reduce shearing stress by absorbing a portion of the patient’s body weight and allowing equal weight distribution throughout the contact area. The orthosis 12 is shaped generally as a footbed to fit securely and removably inside the device 10 between the sole 50 upper surface and the patient’s foot.

[0048] The bottom of a human foot is normally non-planar. Therefore, the top surface of the orthosis 12 similarly is non-planar, rather, it roughly conforms to the planter aspect of a human foot, with recessed areas 14 and 16 to receive the heel and an elevated area 18 corresponding to the arch. The orthosis 12 is made in several sizes to accommodate the several foot sizes of patients. Further, the edges may be trimmed to match foot sizes more exactly or to fit better within the shoe 11.

[0049] The material for the orthosis 12 should be moldable to conform closely to the bottom of an individual patient’s foot. In one embodiment, the orthosis is composed of ethylene-vinyl-acetate (“EVA”) in a closed cell foam. EVA is already used in other medical applications, including orthoses, and is of a proven durability, is biologically inert, and is not known to produce any medical side effects such as rashes or allergies. In contrast, other open and closed cell foams are unsuitable because they overcompress and break down, which ultimately compromise their ability to absorb compressive or impact forces.

[0050] EVA is commercially available in several densities and thicknesses. The most preferable appear to be 2 or 3 pound densities and ⅜ or ¼ inch thicknesses. The foam orthosis 12 has a soft, biocompatible woven cloth material 22 on the outer surface to facilitate putting on and removing shoes.

[0051] Patients often tend to develop ulcerations at the forefoot. One embodiment of the invention addresses this specific wound site by using softer foam at the forefoot and harder foam at the rear. The boundary between the softer foam at the forefoot and harder foam at the rear is a gradual transition. The gradual transition is accomplished by extending the wedge-shaped portion 82 of the softer foam 84 over a wedge-shaped portion 86 of the harder foam 88, as shown in FIG. 5.

[0052] When EVA is used in conjunction with a shoe heel spring (described below), the patient’s weight is distributed between the EVA and the heel spring in about a 40/60 division. The EVA foam thus avoids life-shortening over-compression of the orthosis 12. The allocation of shearing forces between the EVA foam orthosis 12 and the heel spring caused by normal gait lessens the force to the plantar aspect and orthosis 12.

[0053] The EVA orthosis 12 is custom-molded to the patient as follows: Heat is applied to the orthosis 12; then the patient applies his or her foot to the orthosis 12 as shown in FIG. 2 to mirror the plantar aspect of the patient’s foot in the custom orthosis 12. This can be done safely because the foam is heated to only about 160° F. (71° C.), and the patient wears an insulated sock while the foot is in contact with the
heated EVA foam pad. The duration of contact between the foot and the orthosis 12 during this molding process depends in part on the patient’s weight. By exactly matching the foam orthosis 12 to the contours of the bottom of the patient’s foot, the most efficient weight distribution is achieved.

[0054] The molding process described above has long been utilized commercially in custom-fitted ski boots. The patient fitting process of 30 minutes is relatively quick compared to current systems that can take up to several days. This type of EVA material has the ability to be formed with relatively low heat and more quickly than other materials.

[0055] The orthosis 12 may alternatively be a silicone-filled bladder 30 as shown in FIG. 3. The bladder is filled with silicone that hardens to a durometer hardness of 50A on the Shore A hardness scale. The hardness is similar in density to a soft and semi-hard rubber. A silicone that has a hardness of 50A is desirable because it is soft enough to be comfortable to the patient while hard enough to offer adequate foot stability, thereby reducing friction and shearing forces.

[0056] The silicone is injected into a pre-formed bladder envelope using a syringe-like device 34 with an attached mixing chamber 35 prior to the nozzle outlet. The nozzle 37 is designed to fit the bladder inlet port 36. One part of the silicone is the resin, and the other part is the curing agent. When the two parts are mixed, they will solidify into a semi-hard material with a durometer hardness of 50A. After the bladder is filled, the inlet port 36 is sealed using a heat-sealer apparatus (not shown). The inlet port 36 is the same thickness as the bladder and therefore does not interfere with the fit in the shoe or cause any irritation to the patient’s foot.

[0057] The foot bladder orthosis 12 is filled with this highly viscous, 2-part silicone formulation, which conforms to the contours of the bottom of the foot. To effect the molding, the patient applies pressure on the bladder orthosis 12 to create the form of the plantar aspect of the foot. The patient may be either standing or sitting while the foot is making contact with the orthosis 12 bladder to allow for a semi-weight-bearing position of the foot. More silicone can be injected into the bladder while the patient is applying pressure. After approximately 15 minutes, the bladder takes on a permanent form even after the foot is removed from the silicone gel-filled orthosis. Total cure time is 8 hours before the orthosis can be placed in the shoe. This customizes the silicone gel orthosis, resulting in an even distribution of pressure as the patient applies weight with each step. Similar gel pack systems have been used commercially in ski boots and recreational hiking boots. It should be noted that other methods for curing the silicone may also be utilized, such as ultraviolet light.

[0058] The thickness of the silicone-filled orthosis 12 should be from ⅝” to ⅝”. The foot bladder envelope material is 0.010”-0.015” thick polyurethane film. One side of bladder is a polyester felt 38, which is in contact with the patient’s foot (with sock applied). The bladders are die cut and RF sealed (via radio frequency energy) to contain the silicone gel. The pack envelope is with triple-sealed seams to ensure that the pack does not burst even with a heavier person. The pressure on the seams is minimal since the silicone is cured to a semi-hard consistency, and most of the weight is transferred to the shoe spring described below. Several foot sizes can be produced to meet the patient foot sizes. The orthosis 12 is a major component that ensures the efficacy of the device and should be a custom medical device.

[0059] Although the 8-hour cure time is a disadvantage to this system, it is a reliable method of creating a full-contact orthosis, and is an improvement over existing technologies that usually take days to create a custom, hand-made orthosis. The silicone gel is not adversely affected by temperature changes because it is a stable material once it is in the cured state. The silicone filled bladder becomes the orthosis 12 when assembled into the modular walking shoe. Like the EVA foam orthosis 12, the silicone filled bladder orthosis 12 is used in tandem with the heel spring described below, which absorbs most of the patient’s weight.

[0060] The invention features three main non-traditional shoe components to meet the shoe requirements for high-risk patients with diabetes which are designed to accomplish the following objectives:

1. Protect the entire foot utilizing a two-component system;
2. Redistribute pressure away from bony prominences;
3. Provide a stable platform to receive an accommodative orthosis;
4. Provide cushioning that reduces ground-reactive forces to the orthosis and foot;
5. Reduce shearing within the shoe cavity;
6. Maintain stability over a long period of time;
7. Provide a protective covering for the foot;
8. Reduce the time to properly fit patients; and
9. Work as a unit with an accommodative orthosis.

[0070] The malleable shoe upper 42, shown in FIG. 1, is designed to be manually altered around the foot. As such, the upper 42 can be easily redirected away from bony prominences (particularly in the toe area) utilizing standard shoe stretching techniques. The upper 42 is comprised of non-irritating materials with modified seams for reduced irritation. The upper 42 can be easily stretched to accommodate changes in the foot or shrinkage or expansion of upper 42 materials.

[0071] Located directly beneath the orthosis 12 is a sole 50. The sole 50 includes an embedded rigid plate 44 extending from the heel to just proximal to the metatarsal phalangeal joint as shown in FIG. 1. The plate 44 provides a solid foundation for the orthosis 12. The orthosis, as previously noted, is designed to redistribute pressure and protect musculoskeletal abnormalities. As such, the orthosis 12 must be flexible. To maintain the integrity of its shape over time the orthosis 12 must be firmly supported from below to truly support the foot structure. The plate 44 is also critical in distributing ground-reactive forces into the orthosis 12 and foot. The ⅝” length plate 44 significantly redirects these forces, proximal to and away from the high-risk bony prominences of the forefoot.
The sole 50 also preferably includes a forefoot section 51, which is a compressible material such as foam or soft rubber, and provides additional absorption and damping of reaction forces on the foot.

The plate system is designed to provide a foundation for the orthosis. The plate system is built from a nylon/plastic with injected glass fiber (for strength). The plate is permanently attached to the forefoot cushioning material. Neuropathic feet are susceptible to Charcot neuropathology through the possible twisting and torque to the foot caused by uneven surfaces, rocks or unstable ground. The supportive nature of the plate 44 prevents twisting and/or torque of the foot. The plate 44 also serves as an effective barrier in preventing foreign objects from penetrating the shoe and ultimately the foot.

Located directly below the ¾ length plate 44 is the heel element 48, shown in both FIG. 1 and FIG. 4. The active component of the heel 48 is a conical steel spring 46. The primary purpose of the spring 46 is to reduce the overall shock to the orthosis and foot. By reducing the rate of impact the spring effectively curtails ground-reactive forces. By absorbing ground-reactive forces into the shoe the impact on the orthosis 12 is decreased thereby increasing the efficacy and durability of the orthosis 12. The secondary purpose of the spring 46 is to provide an element of stability to the foot by absorbing small to medium deviations in the ground. Normal shoe cushioning devices do not have enough cushioning to effectively absorb deviations in the ground.

The spring 46 may be sleeved in or surrounded by foam rubber or other material to prevent stones or other external objects from interfering with free compression and extension, and also to improve the appearance of the device. Beneath and attached to the spring 46 is a heel bottom 49 to form a smooth surface to contact the floor or the ground.

The union of the orthosis 12 and the shoe should not compromise the accommodative attributes of the orthosis 12 planarly or the shoe dorsally, distally, medially, laterally or posteriorly. There must be a seamless interface making the device function as one unit. Also, the malleability and ease of stretching of the shoe outer must not compromise the integrity of the structure of the shoe. The orthosis 12 is the preferred embodiment will rest in the shoe without any attachment method, as the shoe will contain the orthosis and keep it from moving in any direction. The design of merging the orthosis 12 to the shoe without comprising the orthosis 12 interface with the insensitive foot is addressed by allowing the system to work as a single unit.

The shoe appears very similar in aesthetics to ordinary shoes when assembled, except that the sole 50 and heel 48 are obviously much thicker to accommodate the heel spring. However, the internal design of the shoe is significantly different from an ordinary shoe because it is "malleable" and has spring cushioning properties. The upper of the shoe is malleable to accommodate width of the diabetic foot with standard stretching techniques and musculoskeletal deformities (such as bunions, hammertoes, claw toes, mallet toes, and tailor’s bunions). The upper materials and seams are non-abrasive in nature.

The coil spring cushioning system located below the plate 44 is attached in a semi-permanent fashion to the plate system. The spring is fabricated from tempered steel music wire and exhibits less than 5% fatigue over a 12-month period. The spring is encapsulated in resilient foam. The forefoot 50 (ball of the foot area) cushioning uses 19 mm of extra soft neoprene padding, which is encapsulated in stiffer density outside padding.

In use with patients, the first step is to mold an orthosis 12. As described in some detail above, this involves conforming the orthosis 12 to the plantar aspect of the patient’s foot. If the orthosis 12 is of the EVA closed form type described above, the orthosis 12 is heated to the appropriate temperature, the patient’s foot is sleeved with a protective sock, and the foot is planted onto the orthosis with sufficient pressure to deform the closed cell EVA foam. The EVA foam is then allowed to set in the deformed configuration. If the orthosis 12 is of the silicone gel type described above, the two components of the silicone are injected into the bladder via the bladder injection port, the patient’s foot is planted onto the bladder, to deform the bladder surface, and the silicone is allowed to set and harden in the deformed configuration. The orthosis 12 thus is custom-fitted to the plantar aspect of the particular patient.

The shoe is also customized for the patient by deforming the malleable upper. This is done in accordance with well-known and ordinary shoe upper deformation techniques that have been used in the shoe industry for many years. The difference in this application is that the desired deformation is to accommodate the type of protrusions or unusual configurations that are common to diabetes patients or other patients using the device with foot disorders.

The orthosis 12 is then fitted into the shoe. The shoe comprises the malleable upper, the supporting plate, and the spring-equipped heel. The shoe, so fitted with the custom orthosis 12, is then worn by the patient in the usual manner.

What is claimed is:

1. A shoe adapted for the prevention or treatment of foot wounds in a patient, comprising:
   a shoe upper;
   a sole attached to the shoe upper, the sole including a heel with a spring therein; and
   an orthotic footbed fitted into the shoe upper
2. The shoe of claim 1, wherein the orthotic footbed has an upper surface custom-fitted to the plantar aspect of the patient’s foot.
3. The shoe of claim 2, wherein said orthotic footbed is a heat-deformable foam material.
4. The shoe of claim 2, wherein the orthotic footbed includes a compressible forefoot section and a less compressible rearfoot section, and a transition section of gradually changing compressibility.
5. The shoe of claim 2, wherein said orthotic footbed includes a bladder filled with a hardened liquid material.
6. The shoe of claim 4, wherein said hardened liquid material is silicone injected into the bladder in a liquid condition and hardened with a curing agent.

7. The shoe of claim 2, wherein the upper is malleably deformed to accommodate irregularities in the patient's foot.

8. The shoe of claim 2, wherein said spring is a coil spring having an upper end bearing against the sole and a lower end bearing against a bearing surface of the heel.

9. The shoe of claim 2, wherein the sole includes a rigid plate over the heel end a compressible material at the forefoot.

10. A method for treating or preventing foot ulcers in diabetic patients, comprising: custom fitting an orthotic footbed to the patient's foot; placing the orthotic footbed into a shoe having a spring-loaded heel; and allowing the patient to be ambulatory in the shoe, whereby shearing and impact forces on the patient's foot are partially absorbed by the orthotic footbed and the spring-loaded heel.

11. The method of claim 10, wherein said custom-fitting step includes selecting a footbed of a size appropriate to the patient, the footbed being of a heat-deformable foam; heating the foam to a predetermined deforming temperature; and planting the patient's foot onto the foam to deform the foam surface to conform to the patient's foot.

12. The method of claim 10, wherein said custom-fitting step includes selecting a footbed of a size appropriate to the patient, the footbed being a bladder with an inlet port; injecting the bladder through the inlet port with a liquid material; planting the patient's foot onto the bladder to conform the bladder to the patient's foot; and allowing the liquid material to harden.

13. The method of claim 12, wherein said liquid material includes silicone resin and a hardening agent.