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RESILIENT PROSTHETIC FOOT MADE FROM ELASTIC POLYMERS OF DIFFERENT HARDNESS

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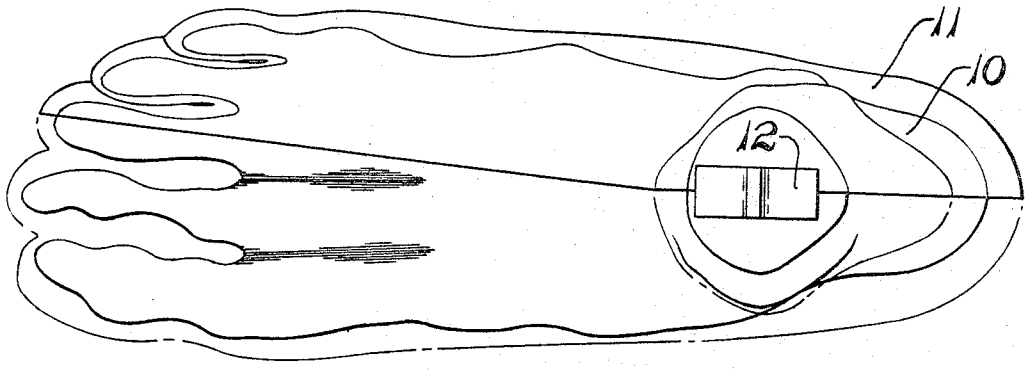


FIG. 1

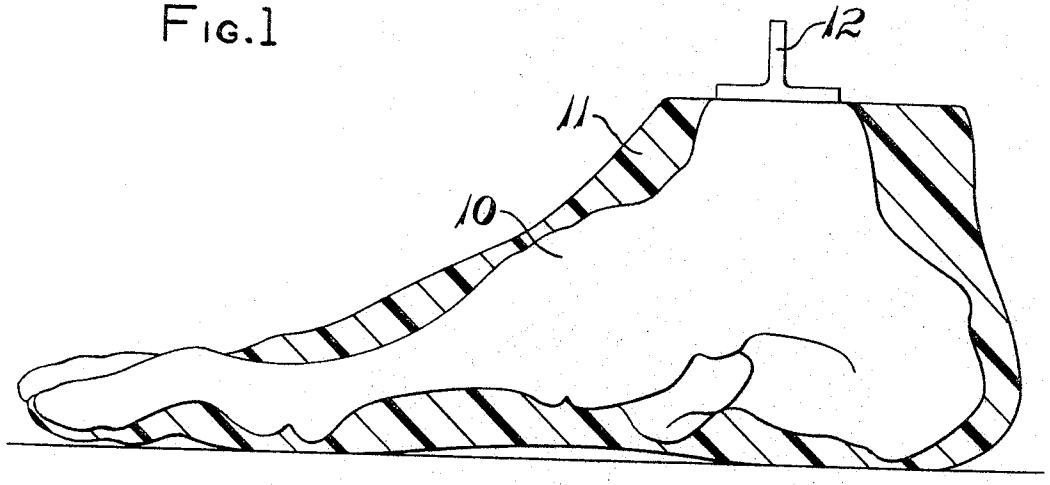


FIG. 2

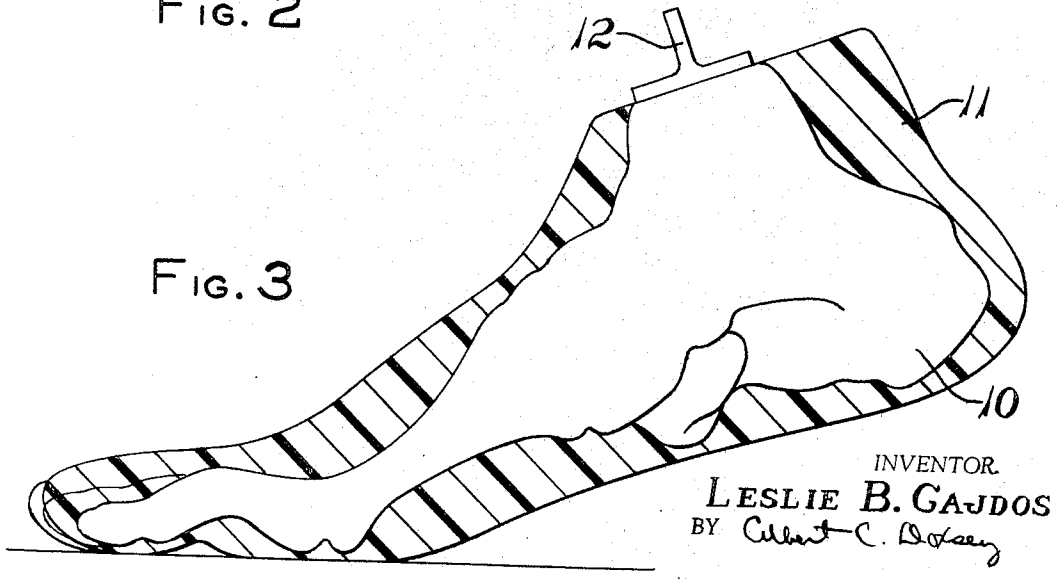


FIG. 3

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RESILIENT PROSTHETIC FOOT MADE FROM ELASTIC POLYMERS OF DIFFERENT HARDNESS

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ABSTRACT OF THE DISCLOSURE

A prosthetic member is provided comprising a true replica of the skeleton of the particular body member, surrounded by a replica of the flesh area of the particular body member.

This invention relates to an artificial body member and more particularly to an artificial foot for replacement of a missing or amputated human foot. This artificial foot is also useful as a mounting device in shoes being tested on certain shoe flexing devices.

Formerly replacement feet were articulated, having a hinged or pivoted ankle joint. In recent years the SACH (solid-ankle-cushion-heel) foot has come into use. The SACH type foot is directly attached to a prosthetic shank and foot action during walking is achieved through the elasticity of the heel and toe portions. The advantage of the SACH foot over the older articulated foot is that it eliminates the simulated ankle joint and reduces much of the wear of moving parts, instability, and noises. The foot with a cushioned heel better simulates plantar flexion of a natural foot. The heel provides shock absorption and is compressed at the beginning of each step. After compression of the heel, the heel cushion expands and the weight of the user shifts to the ball of the foot. The SACH foot contains an internal keel which provides a fulcrum to assist in sharing weight placed on the foot and upon continued rocking of the shank transfers full weight to the ball portion of the foot and causes the toe portion to flex. When the leg is lifted, the toe springs back to its original position. The resilient action of the heel and toe portions assists the user in walking. Since it so closely simulates the natural foot and gait, one is able to walk and use this foot for longer times without fatigue.

Some disadvantages of prior SACH (solid-ankle-cushion heel) type feet are that the parts tend to separate. They are more costly to assemble than the older articulated members. One recent SACH type foot shows a rigid keel surrounded by resilient sections. This structure still tends to suffer delamination between the keel and the surrounding cushion and between this cushion and the sole portion which is cast separately and at its rearward portion is not adhered to the upper portion of the foot. The heel portion of the foot is separately shaped in the form of a wedge which must be precisely shaped and adhered to the upper, to the keel, and to the sole. At a minimum the foot consists of 5 parts, ankle, keel, cushion, heel and sole, all of which must be accurately assembled and fastened together. Currently known artificial feet, while employing as materials of construction such items as leather, plastic foams and the like, still are constructed in large part of wood. Wood portions suffer bumps and bruises and are inherently undesirable in that they offer a potential source for splinters. Furthermore, in the constant flexing to which an artificial foot is subjected, a wood portion tends to wear and deform the softer rubber, plastic, leather or foam portions next to it.

A general object of this invention is to provide an economical and efficient prosthetic foot of the SACH type with improved simulated walking characteristics.

A further object of the invention is to provide a prosthetic foot with a reduced number of parts and reduced tendency for delamination of said parts to occur.

A still further object of the invention is to provide a prosthetic foot which will be more comfortable to the wearer and more economical to manufacture than such articles known in the prior art.

These and other objects and advantages of the invention appear more fully in the following description, made in connection with the accompanying drawings, illustrating the presently preferred embodiment of the invention, wherein reference characters refer to the same parts throughout the several views, in which FIGURE 1 is a top plan cut-away view of an artificial foot made in accordance with the invention, FIGURE 2 is a side view of the foot shown in FIGURE 1 with one portion removed to show the simulated bone structure against the flesh portion of the foot, and FIGURE 3 is a perspective side view showing the foot in flexed position with weight on the ball of the foot.

The unique feature of my artificial foot is that I have essentially duplicated the bone and flesh structure of the human foot and combined these bone and flesh parts into a unitary structure which comes closer to duplicating the exact configuration of the human foot than any prior art structure known.

Once made, my new foot is essentially a one piece unit with no dividing planes between sections and no areas which will weaken by delamination of parts or surfaces. The invention is accomplished by forming a negative mold of the foot bone structure of skeleton **10**. A second negative mold of the flesh of the foot is also prepared. The skeleton or bony structure **10** of the foot is then cast from a suitable elastomeric polymer which is required to be readily meltable and pourable and which, upon setting in the mold, exhibits a Shore A Durometer hardness of 50–85. Materials lower than Shore A hardness of **50** will be too soft and flexible to simulate human bone structure and materials of Shore A hardness above 85 will be too brittle and will fracture easily when the foot is flexed.

The molded foot skeleton **10** is inserted into the negative mold of the entire foot, and is supported therein on positioning pins or in any other convenient manner so that it does not touch the mold surface. Next a second castable, elastomeric polymer is poured into the mold, filling the cavity and completely surrounding the previously cast skeleton to provide an integral covering **11** simulating flesh. A second polymer must exhibit a Shore A hardness of 10–40 after it has set up or cured enough to be removed from the mold. This "flesh" layer fills out the skeleton and forms an accurate reproduction of a human foot. The internal skeleton gives strength and the outer layer duplicates the fleshy parts of the foot.

The shank **12** or other means such as known threaded fastener elements is cast into the ankle portion of the foot for attachment to a footless leg or to a shoe flex testing device.

Any elastomeric polymers which are meltable, castable, and curable (that is, will set up to a solid state after a time with or without the application of heat) and exhibit a Shore A hardness in the specified ranges, are usable in the practice of this invention. Natural rubber, synthetic rubbers such as styrene-butadiene, polyacrylates, butadiene-acrylonitrile, polybutadiene, polyisoprene, polyurethanes, polyvinyl chloride, vinyl chloride-vinyl acetate and similar materials are all useful for either the skeleton, the flesh, or for both parts

when properly modified to give a low Shore A hardness at one time and a high Shore A hardness at another time. Both natural and synthetic polymer foams are well known in the art and can be varied through the desired hardness ranges to form the artificial feet of my invention.

While it is preferable to use a high Shore A Durometer stock for the skeleton and a low Shore A Durometer stock for the flesh of the foot, it is possible to use a single stock with Shore A hardness of 40–60 in the cured state and a single mold—that for the foot alone. Prosthetic feet prepared in this way are better than feet of the prior art in performance, but are not as comfortable as feet made by a proper combination of the skeleton stock and a flesh stock.

I have found that the most preferred polymer stocks to employ for the casting of prosthetic feet are castable polyurethane materials. Liquid castable reaction mixtures are prepared from polyesters or polyethers which are either liquid at room temperature or capable of being melted at relatively low temperatures and which are mixed with polyisocyanates, preferably diisocyanates, and a crosslinking agent such a water, a glycol, or a diamine.

To illustrate the practice of my invention, a skeleton stock is prepared by mixing 100 parts polytetramethyleneether glycol, molecular weight 1000, and 4.5 parts metaphenylenediamine. The mixture is poured into a negative plaster mold previously formed from the skeleton of a foot. Such skeletons are available from medical supply houses. A satisfactory skeleton may also be whittled and carved from wood or molded from clay. Two minutes heating at 285° F. is sufficient to set the casting. After cooling, the mold is removed, leaving a hard bonelike casting **10** of the bone structure of the foot. This casting has a Shore A hardness of 80. A negative plaster mold of a human foot of overall dimensions to fit the prepared skeleton is made next. Preparation of these negative molds is well within the capabilities of one skilled in the art. The cast skeleton **10** is placed within the negative mold of the foot and a second castable polymer mix is prepared by mixing 100 parts of polytetramethyleneether glycol, molecular weight 1000, and 7.3 parts of N,N,N',N'-tetrakis (2-hydroxypropyl) ethylene diamine. This second mix is poured into the mold, surrounds the cast skeleton and is set by a ten minute heat at 285° F. to provide the flesh-like covering **11**. A steel shank **12**, 6" x 1" x ½", is placed to extend 2 inches into the ankle portion of the mold and is cast into place at that point. This shank is readily fastened to a shoe flex testing device. Similar shanks are adapted to fasten the foot to a leg harness for use of this device as a prosthetic foot. After cooling, the mold is removed and we have a replica of the human foot which, on the surface **11**, has Shore A hardness of 40 and also has a hard, bonelike skeletal structure **10** which perfectly matches the structure of the human foot. Suitable harness means, as known in the art, for attachment of an artificial foot to a leg member, are readily incorporated into the artificial foot of this invention in place of steel shank **12**. The polymer then flows around the portions of the fastening means which is in the mold and said fastening means and the cast foot becomes one integral unit as the polymer sets and hardens. No screws, threaded holes, nuts, or bolts are necessary in the foot to fasten the leg harness or flex machine shank to the artificial foot.

In addition to use as a prosthetic device, the artificial foot of this invention is uniquely suited to be inserted in a shoe for flex testing of the shoe on a shoe flexing device. The insertion of a duplicate of the human foot in the shoe as it is placed on the shoe flexing device leads to more valuable test results than when an empty shoe or a shoe containing a conventional wood last is tested. To make this shoe testing even more realistic, ducts can be cast in the artificial foot to provide for the discharge from the foot to the shoe of artificial perspiration. Resistance wires can also be cast into the foot to provide for heating the foot to body temperature.

I claim:

1. An artificial foot comprising a casting of at least two polyurethane polymers, the first of said polymers forming a true replica of the skeleton of a human foot and having Shore A hardness of 50–85, the second of said polymers forming the flesh portion of said foot and having Shore A hardness of 10–40, said flesh portion completely enclosing said skeleton portion, said flesh portion in outer contour exactly duplicating the flesh structure of the human foot.

2. A flexible prosthetic foot comprising the combination of two separate castings, an inner casting (1) and an outer casting (2), said casting (1) being made from an elastomeric polymer of 50–85 Shore A Durometer hardness and duplicating in shape and size the bony skeleton of the human foot and said casting (2) being made from an elastomeric polymer of Shore A Durometer hardness of 10–40, said casting (2) being formed around said casting (1) in such a manner that said casting (2) duplicates in shape, feel and position the flesh portion of the human foot and said casting (1) duplicates the positon of the skeletal portion of said foot.

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