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Johnson

[11] **3,782,390**

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[54] **PEDICURE PROSTHESIS FOR THE METATARSAL ARCH OF THE FOOT**

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[21] Appl. No.: **165,610**

[52] **U.S. Cl.** **128/595,** 128/90, 264/45, 264/222, 264/DIG. 30

[51] **Int. Cl.** **A41f 5/14**

[58] **Field of Search** ..... 128/595, 594, 90, 128/89; 264/45, 222, DIG. 30

[56] **References Cited**

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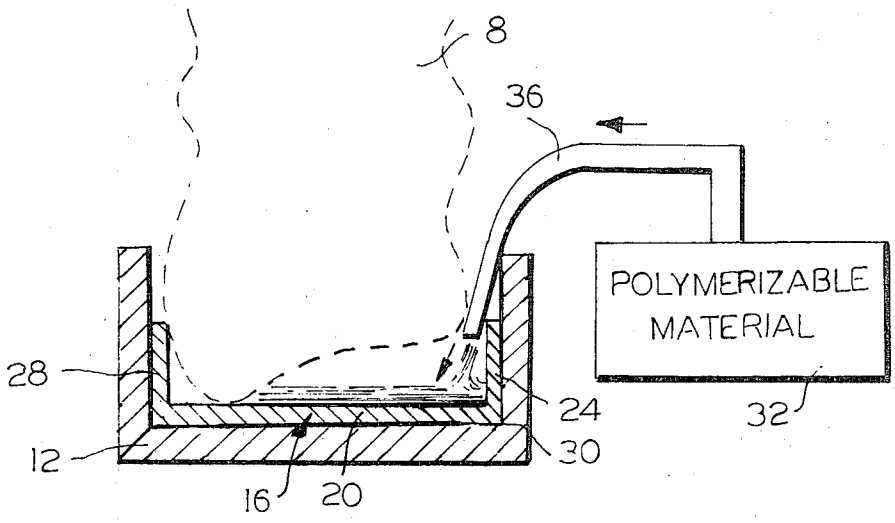
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Attorney—Arnold B. Christen et al.

[57] **ABSTRACT**

A support for the metatarsal arch of the foot is formed by injection of a self-curing non-foamable fluid material into the arch support enclosure. This fluid material automatically cures into a rigid support or prosthesis for the arch of the foot. This polymerizable material is normally contained in either a insert under the foot or by a balloon like material, in either case the polymerizable material is pumped or injected into the resulting enclosure. The same method can be used to form in situ prosthesis casts for any part of the body, i.e., to form splints, braces, etc., contured directly to the portion of the human body for which it is designed to lend support. The self-curing material is preferably a cross-linkable prepolymerized material which includes an initiator, and the self-curing is achieved by the application of mild temperatures, e.g., 120° F.

14 Claims, 5 Drawing Figures



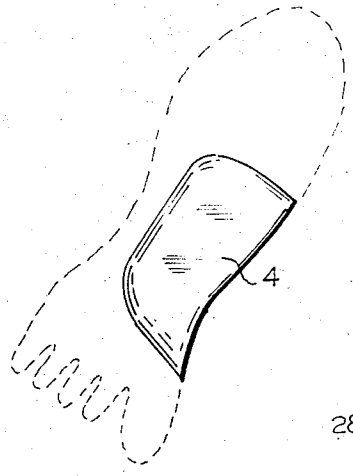


FIG.1

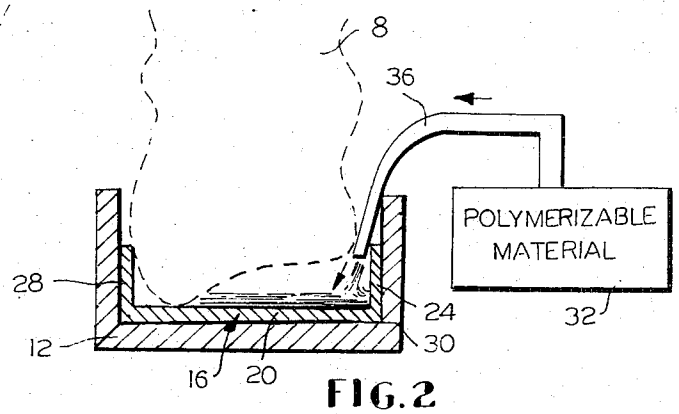


FIG.2

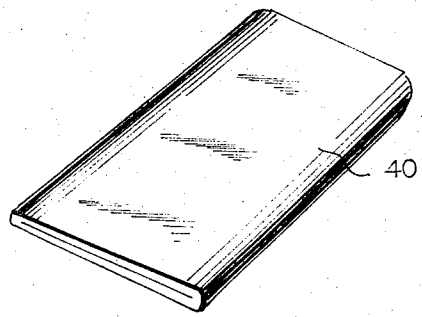


FIG.3

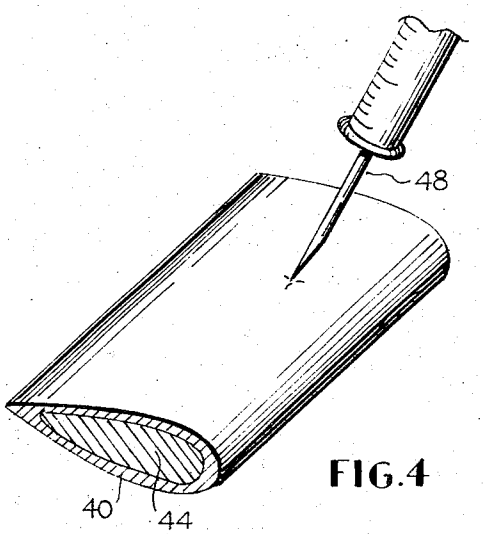


FIG.4

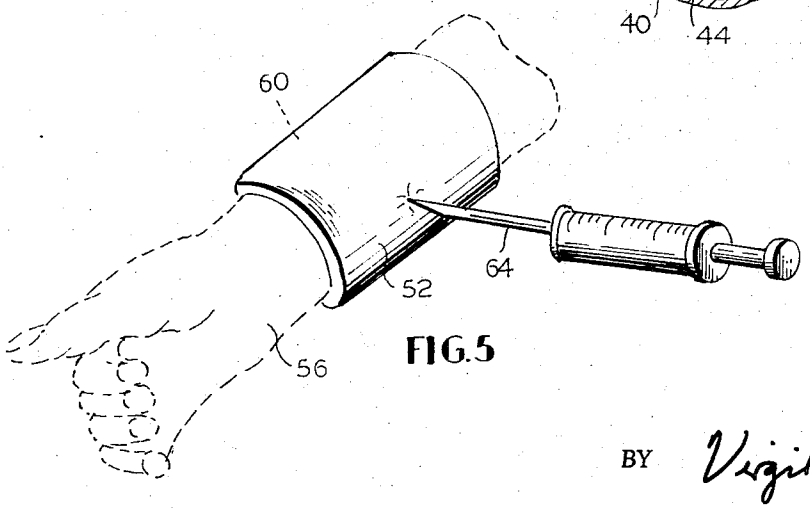


FIG.5

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PEDICURE PROSTHESIS FOR THE METATARSAL ARCH OF THE FOOT

PRIOR ART

Foamed thermoplastic material used as prosthesis are known.

U.S. Pat. No. 3,257,742 shows a soft, readily deformable foot support for shoes. The support has a plastic or puttylike consistency and is a foot support that is readily impressionable in response to pressure exerted thereon by the foot. After the foot pressure is removed, the support returns to its original shape. The support is essentially a cured epoxy resin or linear polybutadiene that has these characteristics, and an outer encompassing layer, such as leather, at col. 3, lines 73–74, the uncured resins are stated to be flowable so that they take the shape of the container into which they are poured. This patent does not disclose in situ curing in a shoe to set up a permanent foot support that is tailor molded in effect to aid each foot problem. The patent further discloses the use of a hard non-foamed prosthesis.

Likewise with U.S. Pat. No. 3,402,411 which is drawn to a ski-boot ankle support and the use of polymers which lend themselves to ready molding when pressure is applied with slow shape recovery.

U.S. Pat. No. 3,407,406 is directed essentially to a ski-boot and it uses a flexible, hollow material filled with a substance which holds its shape a long time or until an outside pressure is exerted. The patent does not disclose a non-foamable, rigid, non-deformable prosthesis which is prepared from a self-curing polymerizable material.

BROAD DESCRIPTION OF THE INVENTION

The invention involves a process for preparing a prosthesis for supporting or restraining a part of the body. The process, broadly involves placing a prosthesis enclosure on the affected portion of the body; placing a fluid, self-curing non-foamable material in the prosthesis enclosure; and permitting the fluid self-curing material to cure in situ to form a rigid cured non-foamed material which conforms to the shape of the affected portion of the body. The most preferred fluid self-curing material is polymethyl methacrylate dissolved in monomeric methyl methylacrylate (1:1 weight ratio), and the material contains about 0.1 percent of acetyl peroxide as a catalyst (initiator).

In one embodiment, the prosthesis enclosure is first placed in a shoe, wherein the affected part of the body is the metatarsal arch of a foot and wherein the prosthesis enclosure is placed on the affected portion of the body by placing the foot in the shoe. Preferably, pressure is placed on or applied to the fluid self-curing material before it completely cures so that the fluid self-curing material takes the shape of the metatarsal arch. The pressure can be applied by the weight of the body being shifted onto the foot. One sub-embodiment involves a prosthesis enclosure which is a sealed envelope with at least its top surface being elastic. In this sub-embodiment the fluid self-curing material is placed in the prosthesis enclosure by piercing a side of the prosthesis enclosure with an elongated hollow tube device and force injecting the fluid self-curing material through the elongated hollow tube device into the prosthesis enclosure. The hollow tube device is removed after the fluid self-curing material is placed in the prosthesis enclosure and the side of the prosthesis enclosure is rapidly sealed. Preferably the region of the side of the prosthesis enclosure, which is pierced by the hollow tube device, is self-sealing when the hollow tube device is removed.

In another sub-embodiment, the preferred embodiment of the invention, the prosthesis enclosure is a rigid insert that is placed on or affixed to the insole of the shoe. The insert comrises: a flat plate that extends across the width of the insole and extends lengthwise at least across the metatrasal arch of the foot; a low side wall on the side away from the metatarsal arch; and a high side wall which completely covers the arch when the foot is inserted into the shoe. The foot serves as the top of the prosthesis enclosure. The fluid self-curing material is placed in the prosthesis enclosure by means of a tube inserted between the high side wall and the foot. The tube is rapidly removed after the fluid self-curing material is placed in the prosthesis enclosure.

In still another sub-embodiment of the invention, a cast is placed over the prosthesis enclosure before the fluid self-curing material is placed in the prosthesis enclosure. This sub-embodiment can be used whenever a cast is used, for example, with broken limbs.

The invention also involves the prosthesis for supporting or restraining a part of the body. The prosthesis includes a prosthesis enclosure on the affected part of the body and a rigid, polymerized, non-foamed material, within the prostheiss enclosure, which conforms to the shape of the effected portion of the body. The prosthesis can be one where the prosthesis enclosure is located between the affected part of the body and a cast. The prosthesis can be one where the prosthesis enclosure is located on the insole of a shoe where the metatarsal arch of a foot is located. This latter prosthesis can be one where the prosthesis enclosure is a sealed enclosure. Or, preferably, this latter prosthesis can be one where the prosthesis enclosure is a rigid insert that is placed on or affixed to the insole of the shoe. The insert comprises: a flat plate that extends across the width of the insole and extends lengthwise at least across the metatarsal arch of the foot; a low side wall on the side away from the metatarsal arch; and a high side wall on the side of the metatarsal arch which completely covers the arch when the foot is inserted in the shoe. The foot serves as the top of the prosthesis enclosure.

DETAILED DESCRIPTION OF THE INVENTION

The objects and advantages of the invention become apparent to those ordinarily skilled in the art in the following description of the invention as illustrated in the accompanying drawing, in which;

FIG. 1 is a top view of the prosthesis of this invention;

FIG. 2 is a cross sectional view of one embodiment of preparing the prosthesis;

FIG. 3 is a partial perspective view of another embodiment of this invention, namely, the balloon-like enclosure;

FIG. 4 is a partial perspective view illustrating the injection of the polymerized material into the balloon-like enclosure; and

FIG. 5 is a partial perspective view illustrating the preparation of a prosthesis which in effect is an arm cast.

FIG. 1 illustrates a rigid non-foamed arch support 4 and the transverse or metatarsal arch of the foot. FIG. 2 illustrates the embodiment of the invention where the prosthesis is produced in situ. Foot 8 is inserted into

shoe **12.** Shoe **12** contains prosthesis enclosure **16** which consists of base plate **20,** side plates **24** and **28.** Prosthesis enclosure **16** fits into the bottom of shoe **12** so that when foot **8** is inserted into shoe **12** the metatarsal arch is completely enclosed by prosthesis enclosure **16.** Base plate **20** must be wide enough and long enough so that the circumference areas of the arch are in contact therewith so that a seal is formed between foot **8** and base plate **20.** The bottom surface of base plate **20** can contain an adhesive to allow prosthesis enclosure **16** to adhere to the inner sole and remain in the desired position. Side plate **28** is located on the outer extermity on the foot, forming a seal by contacting the side surface of the sole. Side wall **24** is located at the inner extremity of the foot, contacts the side of the foot, and is so shaped as to form a seal with the side of the foot. Self curing material **32** is injected into the area enclosed by prosthesis enclosure **20** and foot **8.** Material **32** is injected by means of tube **36,** the tip of which is inserted into the enclosure between side wall **24** and foot **8** as shown in FIG. **2.** Material **32** is pumped into the enclosure between foot **8** and piece **16** as shown in FIG. **2.** The entire enclosure is filled up with material **32** and the tip of tube **36** is removed. Material **32** is then self polymerizable, forming in situ a non-foamable rigid prosthesis which conforms to the metatarsal arch and gives excellant support thereof. The form and shape of the metatarsal arch support prosthesis is determined by the contours of the foot of the wearer who is exerting pressure on the prosthesis as, or immediately after, the self-curing fluid system is injected (before complete curing).

Another embodiment of the invention is illustrated in FIGS. **3** and **4.** Prosthesis enclosure **40** is illustrated in a deflated condition in FIG. **3.** Prosthesis enclosure **40** is a completely sealed unit and is placed in the shoe in a manner so that it is under the entire metatarsal arch and surrounding foot portion. Enclosure **40** is made of a deformable material at least part of which is self-sealing after puncture by a sharp object. Any self-sealing material may be used which is compatable with the foot and the self-curing material. While the self-sealing portion is preferred, the puncture area can be sealed by known methods such as those given in U.S. Pat. Nos. 2,646,707 and 2,803,284 which provide means for injecting self-curing material **44** into the internal space of enclosure **40** by means of a hollow sharp pointed instrument **48.** Any sharp hollow pointed instrument, such as, a hypodermic needle, can be used for puncturing enclosure **40** and force injecting self-curing material **44** into the internal space of enclosure **40** so that it may cure to form a rigid non-foamable prosthesis. The bottom surface of the arch support prosthesis may be coated with an adhesive to allow the device to be attached to the inner sole securely enough to remain in the desired position in the footwear.

FIG. **5** illustrates the universality of using this invention to form a rigid supporting conformed non-foamable prosthesis whereever any cast or similar enclosure is used on a human or animal. FIG. **5** specifically illustrates the use of the prosthesis in conjunction with cast **52** on limb **56.** Cast **52** can be made of any conventional cast material, such as, plaster of Paris, or can be a relatively deformable or elastic material, such as, rubber. Between limb **56** and cast material **52,** a prosthesis enclosure such as **40** in FIG. **3** is inserted and encompasses all or part of limb to illustrate this variation of this invention. Prosthesis enclosure **60** can be elongated and wrapped around limb **56** before cast **52** is applied or it can be doughnut shaped and inserted over limb **56** before case **52** is applied. The self-curing material is injected into prosthesis enclosure **60** by means of a hypodermic needle **64.** Cast **52,** when it is relatively elastic or when it is rigid, acts in effect as a restraining force which causes the formed prosthesis to conform to the outline of the limb. Thus, if the limb has been broken, it is in effect a cast which is superior to any known cast. The self-curing material which is used to form the prosthesis should broadly be a thermal plastic material which polymerized or cures in situ after being placed in the prosthesis enclosure, should not give off any gas during curing, should be gaseous or liquid, should have the same volume in the prepolymerized states as in the resulting polymerized state (i.e., as after curing), and which should be nontoxic or nonharmful to human or animals, particularly the effected skin area. The term self-curing material encompasses an admixture of any cross-linkable prepolymerized material and any ethylenically unsaturated monomer which do not cure to any substantial degree until the admixture is placed in the prosthesis enclosure. This encompasses curable systems which are admixed with a catalyst and immediately injected into the prosthesis enclosure.

The cross-linkable prepolymerized materials are broadly unsaturated polymerizable materials which are generally conventional classes of known resisn such as unsaturated polyester resins.

The preferred cross-linkable prepolymerized materials are the poly(esters of methacrylate), and the preferred poly(ester of methacrylate) is poly(methyl methacrylate).

Any of the ethylenically unsaturated monomers listed below [(**1**) to (**6**)] can be prepolymerized to be used as the cross-linkable material.

The most preferred polyester resins are prepared by the esterification of alpha, beta-unsaturated polybasic acids, (preferably a dibasic acid) and a polyhydric alcohol (preferably a dihydric alcohols). Certain compounds of this type may be indicated generically as follows: -M-G-M-G-M-G, where -M- represents an unsaturated dibasic acid residue and -G- represents a dihydric alcohol residue. Modifying saturated dibasic acids may also be used in the polyester resin compositions. Representative dihydric alcohol and unsaturated polybasic acids are shown below.

In preparing unsaturated polyester which may be employed in the practice of the present invention, the alcohol component may comprise one of the group of solid polyethylene glycols designated as "Carbowax." Polyethylene glycols such as the Carbowaxes are understood to have molecular weights above 300. Those most useful for this invention have weights below 4,000 and preferably are in a range of about 1,000 to 2,000, e.g., 1,500.

Examples of dihydric alcohols are propylene glycol, ethylene glycol, trimethylene glycol, 2,2-dimethylpropanediol, 1,2-butanediol, 2,3-butanediol, 1,3-butanediol, 1,4-butanediol, 1,5-pentanediol, 3-methyl-1,3-butanediol, pinacol, 2-methyl-2,4-pentanediol, 1,5-hexanediol, 1,8-heptanediol, 1,8-octanediol, 1,9-nonanediol, 1,10-decanediol, 1,11-hendecanediol, 1,12-dodecanediol, 1,13-tridecanediol, 1,14-tetradecanediol, 1,15-pentacanediol, 1,16-

hexadecanediol, 1,18-octadecanediol, 1,24-tetracosane and 1,30-tricacontanediol. Examples of trihydric alcohols are glycerol, 1,2,3-butantriol and 1,1,1-trihydroxymethylethane. Examples of higher polyhydric alcohols are 1-1,2,3,4-butanetetrol, tetrahydroxyneopentane, D-arabitol, adonitol, L-arabitol, xylitol, sorbitol, D-mannitol, o-iditol, dulcutol, L-tatitol, styracitol, perseitol, volemitol, cellobiitol, lactitol, melibiitol, maltitol.

The acid component usually comprises an alpha, beta-ethylenically unsaturated polycarboxylic acid such as maleic, fumaric or itaconic acid, or the well-known derivatives of these polycarboxylic acids having ethylenic unsaturation in alpha-beta relation to the carboxyl group. Polybasic acids such as aconitric acid, tricarballylic acid or citric and may also be employed. A plurality of such acids may also be mixed with each other, if so desired. In many instances, it may be desirable to include a dicarboxylic acid free of ethylenic unsaturation. Examples of this latter type of dicarboxylic acid include phthalic acid or terephthalic acid, which although they contain double bonds in the benzene ring, do not undergo addition reaction with monomer compounds and may, therefore be considered as being the equivalent of saturated compounds. Likewise, aliphatic dicarboxylic acids such as succinic acid, adipic acid, sebacic acid, or azelaic acid, may be substituted for a part of the alpha, beta-ethylenically unsaturated dicarboxylic acid. The proportion of the non-ethylene acid with respect to the alpha, betaethylenically unsaturated acid is susceptible of wide variation. A molecular proportion of 0.25 to 12 moles of saturated acid per mole of unsaturated acid is usually used for commercial applications. Also acid anhydrides of these dicarboxylic acids can be used instead of the dicarboxylic acids.

The cross-linked prepolymerized materials can be prepared by any conventional method. In preparing a polyester, a small excess (usually five or 10 percent) of the dihydric alcohol is usually employed. The conditions of the esterification reaction are those conventionally employed in preparing polyesters. For example, the mixture of the alcohol and the acid is heated in a vented container or under an inert atmosphere until the water of reaction is expelled from the system, which usually occurs in a temperature range of about 150° to 210° C. The reaction is continued until the acid value is reduced to a reasonable low point, e.g., within a range of about five to 50, or until the mixture becomes highly viscous or even solid when it is cooled. Usually these conditions are attained in a period of 2 to 20 hours. In the event the reaction is concluded before the product becomes infusible and insoluble because of the advanced stage of polymerization. The product is then blended with the ethylenically unsaturated monomer in such a manner as to maintain the temperature of the blend below 150° F.

The preferred ethylenically unsaturated monomers which can be used as the cross-linking agent are the esters of methyacrylate and the most preferred is methyl methacrylate.

The ethylenically unsaturated monomers which can be used as the cross-linking agent may be selected from the following general list:

1. Monoolefinic hydrocarbons, that is, monomers containing only atoms of hydrogen and carbon, such as styrene, alpha-methyl styrene, alpha-ethyl styrene, alpha-butyl styrene, vinyl toluene and the like;

2. Halogenated monoolefinic hydrocarbons, that is, monomers containing carbon, hydrogen and one or more halogen atoms such as alpha-chlorostyrene, alpha-bromo-styrene, 2,5-dichlorostyrene., 2,5-dibromostyrene, 3,4-dichlorostyrene, 3,4-difluorostyrene, ortho-, meta and para- fluorostyrenes, 2,6-dichlorostyrene, 2,6-difluorostyrene, 3-fluoro-4-chlorostyrene, 2,4,5-trichlorostyrene, dichloromonofluorostyrene, chloroethylene (vinyl chloride), 1,1-dichloroethylene (vinylidene chloride), bromoethylene, fluorethylene, iodoethylene, 1,1-dibromoethylene, 1,1-difluoroethylene, 1,1-diiodoethylene and the like;

3. Esters of organic and inorganic acids such as vinyl acetate, vinyl propionate, vinyl butyrate, vinyl isobutyrate, vinyl avalerate, vinyl caproate, cinyl enanthate, vinyl benzoate, vinyl toluate, vinyl p-chlorobenzoate, vinyl o-chlorobenzoate, vinyl m-chlorobenzoate, and similar vinyl halobenzoates, vinyl p-methoxybenzoate, vinyl o-methoxybenzoate, vinyl p-ethoxybenzoate, methyl methacrylate, ethyl methacrylate, propyl methacrylate, butyl methacrylate, amyl methacrylate, hexyl methacrylate, heptyl methacrylate, octyl methacrylate, decyl methacrylate, methyl crotonate, ethyl crotonate, and ethyl tiglate, methyl acrylate, ethyl acrylate, propyl acrylate, isopropyl acrylate, butyl acrylate, isobutyl acrylate, amyl acrylate, hexyl acrylate, 2-ethylhexyl acrylate, heptyl acrylate, octyl acrylate, 3,5,5-trimethylhexyl acrylate, decyl acrylate, and dodecyl acrylate, isopropenyl acetate, isopropenyl priopionate, isopropenyl butyrate, isopropenyl valerate, isopropenyl caproate, isopropenyl enanthate, isopropenyl benzoate, isopropenyl p-chlorobenzoate, isopropenyl o-bromobenzoate, isopropenyl m-chlorobenzoate, isopropenyl toluene, isopropenyl alpha-chloracetate and isopropenyl alpha-bromopropionate;

Vinyl alpha-chloroacetate, vinyl alpha-bromoacetate, vinyl alpha-chloropropionate, vinyl alpha-bromopropionate, vinyl alpha-iodopropionate, vinyl alpha-chlorobutyrate, vinyl alpha-chlorovalerate and vinyl alpha-bromovalerate;

Allyl chlorocarbonate, allyl formate, allyl acetate, allyl propionate, allyl butyrate, allyl valerate, allyl caproate, diallyl phthalate, diallyl succinate, diethylene glycol bis (allyl-carbonate), allyl 3,5,5-trimethylhexoate, allyl benzoate, allyl acrylate, allyl crotonate, allyl oleate, allyl chloroacetate, allyl trichloroacetate, allyl chloropropionate, allyl chlorovalerate, allyl lactate, allyl pyruvate, allyl aminoacetate, allyl aminoacetate, allyl acetoacetate, allyl thioacetate, diallyl-3,4,5,6,7,-7-hexachloro-4-endomethylene tetrahydrophthalate, as well as methallyl esters corresponding to the above allyl esters, as well as esters from such alkenyl alcohols as beta-ethyl allyl alcohol, beta-propyl allyl alcohol, 1-buten-4-ol, 2-methyl-buten-1-01-4, 2(2,2-dimethyl propyl) -1-buten-4-ol and 1-pentene-4-ol;

Methyl alpha-chloroacrylate, methyl alpha-bromoacrylate, methyl-alpha-fluoroacrylate, methyl alpha-iodoacrylate, ethyl alpha-chloroacrylate, propyl alpha-chloroacrylate, isopropyl alpha-bromoacrylate, amyl alpha-chloroacrylate, octyl alphachloroacrylate, 3,5,5-trimethylhexyl alpha-chloroacrylate, decyl alpha-chloroacrylate, methyl alpha-cyano acrylate, ethyl alpha-cyano acrylate, amyl alpha-cyano acrylate, amyl alpha-cyano acrylate and decyl alpha-cyano acrylate;

Dimethyl maleate, diethyl maleate, diallyl maleate, dimethyl fumarate, dimethallyl fumarate and diethyl glutaconate;

4. Organic nitriles such as acrylonitrile, methacrylonitrile, ethacrylonitrile, crotonitrile, and the like;

5. Acid monomers such as acrylic acid, methacrylic acid, crotonic acid, 3-butenoic acid, angelic acid, tiglic acid and the like;

6. Amides such acrylamide, alpha-methyl acrylamide, N-phenyl acrylamide, N-methyl-N-phenyl acrylamide, N-methyl acrylamide, and the like.

The total mols of acid constituents of the unsaturated polybasic acid (and any saturated polybasic acid) are preferably balanced stoichiometrically with the polyfunctional alcohol.

Because of the mature of the invention, the preferred monomers are liquid compounds soluble in the cross-linkage prepolymerized material. This means that the cross-linked prepolymerized material is a homopolymer and the monomer is the same monomer from which the cross-linkable prepolymerized material is formed, because the liquid monomer is then most likely soluble in the prepolymerized material and vice versa Solvents can be used, but very little if any solvent should be used because of the enclosed curing (cross-linking) area used in this invention. Examples of useful solvents and diluents are: alcohols, such as, methanol (b.p. = 64° C.), ethanol (b.p. = 78° C), isopropanol (b.p. = 80° C.), propanol (b.p. = 95° C.), N-butyl alcohol (b.p. = 118° C.), secondary butyl alcohol (b.p. = 99° C.), isobutyl alcohol (b.p. = 107° C.), and methyl isobutyl carbinol (b.p. = 131° C.); glycol ethers, such as, ethylene glycol monomethyl ether (b.p. = 125° C.), ethylene glycol monoethyl ether (b.p. = 136° C.), ethylene glycol monobutyl ether (b.p. = 171° C.), diethylene glycol monomethyl ether (b.p. = 194° C.), diethylene glycol monoethyl ether (b.p. = 195° C.) and diethylene glycol monobutyl ether (b.p. = 230° C.); ketones such as, acetone (b.p. = 56° C.), methyl ethyl ketone (b.p. = 79° C.), methyl isobutyl ketone (b.p. = 115° C.) and isophones (b.p. = 207° C.); aliphatic hydrocarbons, such as hexane, (b.p. = 155° C.) and heptane (b.p. = 201° C.); esters such as, ethyl acetate, amyl acetate and butyl acetate; aromatic hydrocarbons such as benzene (b.p. = 80° C.), toluene (b.p. = 110° C.) and mixed xylene (b.p. = 275° C.); and halogenated hydrocarbons such as, chloroform, perchloroethylene, carbon tetrachloride (b.p. = 76° C.) and trichloroethylene (b.p. = 86° C.). Water, and water plus another dilutent (water is usually not a solvent for organic materials) can be used, but neither is preferred. A dilutent means that the carrier is not a solvent for the polymeric constituents, catalyst, etc., being used.

In general, the monomer component or components may be employed over a relatively broad range, but usually, the amount thereof upon a weight basis will be less than that of the prepolymerized material. Usually, the percentage of monomer will fall within a range of about 10 to 45 percent by weight of the total mixture of the prepolymerized material and monomer. The preferred range of monomer is about 20 to 40 percent in most instances.

The curing time of the systems varies between about 1 minute and about 24 hours. This time span depends, in part, upon the type of prepolymerized material, the monomer, the amount of catalyst, the amount of inhibitor, and so forth. The curing temperature of the resin systems varies, and preferably the resin system can be cured at room temperature (15° to 30° C.).

The curing temperature should not be so high that the wearer cannot keep his foot, etc., in the shoe when the rigid form of the prothesis is being prepared by the curing. Also the curing time should be two hours or less for the comfort of the wearer.

As the scope of useful resin systems is extensive, the type of promotor which can be used in those systems is also extensive. A few exemplary promotors are given in the following paragraphs.

One of the promotor types which can be used in the resin system is a cobalt salt which is capable of being dissolved in the resinous composition. Suitable soluble promoters are cobalt octoate or any other higher fatty acid salt of cobalt. The amount of cobalt salt can be varied from about 0.001 to 0.3 percent of the salt calculated as dissolved metallic cobalt based on the total weight of the resin compounds, catalysts and promoter mixture employed. On the same basis, the preferred amount of cobalt metal ranges from about 0.05 to 0.15 percent.

The vanadium promoters disclosed in U.S. Pat. No. 3,333,021 are useful.

Another promotor type material is a variety of amine promoters. Suitable amine promoters are disclosed in U.S. Pat. No. 2,480,928. The promoters are described therein as tertiary monoamines which contain attached to the nitrogen atom two functionally aliphatic radicals selected from the group consisting of alkyl hydrocarbons, hydroxy-substituted alkyl hydrocarbons and aralkyl hydrocarbons and one aromatic radical selected from the group consisting of aryl hydrocarbons, azo-substituted aryl hydrocarbons, amino-substituted aryl hydrocarbons and salts thereof. Specific examples of this class are the following: dimethylaniline, diethylaniline, di-n-propyaniline, dimethyl-p-toluidine, dimethyl-o-toluidine,dimethyl-alpha-naphthylamine, methyl benzyl aniline, p-dimethylamino-azobenzene, N,N-di-methyl-m-aminophenol, p-dimethylaminophenyl oxalate, p-dimethylaminobenzaldehyde, p-dimethylaminophenyl acetate, and p-hydroxy-N,N-di(beta hydroxyethyl) aniline. Additionally, the promotor can be a tertiary alkyl amine, a hydroxy alkyl amine or an acid salt thereof as a promoter. Examplary of these types of promoters are diethylmethylolamine, triethylamine, triisopropylamine, trimethylamine, triisopropanolamine, ethyl diethanolamine hydrochloride and the like. Tertiary polyamines are also effective for use in the instant manner, such as for example, tetramethylbutanediamine. The amount of amine promoter useful in the practice of this invention varies between about 0.05 to 1.0 percent based on the resin components, catalyst and promoter. These amine promoters can be used in conjunction with the above cobalt promoters.

The resin systems of this invention (containing the monomer and the prepolymerized material) are readily cured by any conventional catalyst. The preferred catalysts are organic peroxides most preferably diocyl peroxides, and the preferred organic peroxide is acetyl peroxide. Examples of other useful diacyl peroxides are caprylyl peroxide, lauroyl peroxide, decanoyl peroxide, 2,4-dichlorobenzol peroxide, p-chlorobenzoyl peroxide, pelargonyl peroxide and propionyl peroxide. Other useful organic peroxide catalysts include: peroxyesters, such as, tert.-butyl peroxyacetate, tert.-butyl perox-

yisobutyrate, tert.-butyl peroxypivalate, tert.-butyl peroxybenzoate, tert.- butyl peroxy (2-ethylhexanoate), 2,5-dimethyl-2,5-bis-(benzoylperoxy) hexane, 2,5-dimethylhexane-2,5-diperoctoate, and di-tert.-butyl diperoxyphthalate; alkyl peroxides, such as, di-tert. butyl peroxide, n-butyl-4,4-bis(tert.-butylperoxy) valerate, 2,5-dimethyl-2,5-bis (tert.-butylperoxy) and 2,5-dimethyl-2,5-bis (tert.-butylperoxy) hexyne-3; hydroperoxides, such as, tert.-butyl hydroperoxide, a-cumyl hydroperoxide and 2,5-dimethylhexane-2,5-dihydroperoxide; and ketone peroxides, such as, methyl ethyl ketone peroxides, cyclohexane peroxides and bis(1-hydroxyclohexyl) peroxide.

Preferably the catalyst is used in an amount small enough to get a fast cure without excessive heat production. Usually from 0.01 to 2 percent of catalyst, based on the total weight of the resin components, are used. Preferably about 0.1 percent of catalyst is used.

The resin systems of this invention can also contain other compatible additives, such as, dyes, reinforcing materials (asbestos, chopped glass fibers), etc. The fluid polymerizable composition can also contain compatible plasticizers, such as, di-n-butyl styryl phosphonate and dimethyl phthalate; and compatible fillers, such as, silicon dioxide, titanium dioxide, calcium carbonate, silica and carbon black. The fluid polymerizable composition can also contain a compatible conventional inhibitor.

To add structural body to the cured polymer resins, materials, such as styrene, vinyl toluene, α-methylstyrene, dimethylstyrene, the methyl-α-methylstyrenes, α-bromostryene, β-bromostyrene, α-chlorostyrene, β-chlorostyrene, diallyphthalate, vinyl acetate, methyl methacrylate and divinylbenzene, can be added to the uncured polymer resins so that they can be copolymerized with the other monomer components.

The systems of this invention can be stored for long times, either separately or mixed (provided in the latter instance a catalysted mixture must be heated to initiate the curing to any significant degree).

The surface of any prosthesis can be covered with a soft flexible material which makes it soft and comfortable to the skin. For example, the top of a foot prosthesis may be covered with leather, or simulated leather. The surface of the prosthesis not contacting the skin may be adhered, for example, by gluing, to the cast or shoe to insure the prosthesis remains securely in the desired position in relationship to the cast or footwear and the body part.

A package to be purchased by the shoe wearer could contain one prosthesis for each foot, the injection devices and material to be injected, and detailed instructions for the mechanism to be utilized in the injection of the thermoplastic fluid into the hollow interior of the prosthesis. The actual injection of the materials into the cavity of the arch support could be done as a skilled service by the trained footwear salesman or could be done by the purchaser of the articles of footwear. First aid kits or hospital kits could be similarly packaged and sold for use when casts are applied.

1.0 mole percent is 0.01 mole per 100 grams of resin. Weight percent or percent by weight as used throughout this application, unless otherwise specifically stated, is defined conventionally as grams per 100 grams of resin.

The following examples illustrate this invention. All percentages and parts therein are by weight, unless otherwise stated.

EXAMPLE

A foot was placed in a show as shown in FIG. 1, the prosthesis enclosure **16** being made of aluminum. Poly(methyl methacrylate) was dissolved in monomeric methyl methacrylate in a ratio of 1:1 by weight. The solution was then admixed with 0.1 percent by weight, based on that composition, of acetyl peroxide an initiator. The catalyzed solution was injected into the enclosed area by means of line **36**. Line **36** was removed. The catalyzed solution rapidly polymerized at 120° F. and was allowed to self cure to a rigid prosthesis for the metatarsal arch of the foot. A leather covering was placed between the prosthesis and the foot.

What is claimed is:

1. The process for preparing a prosthesis for supporting or restraining a part of the body which comprises: (*a*) placing a fluid, self-curing, non-foamable material in said prosthesis enclosure, said fluid self-curable material being comprised of an admixture of a cross-linkable prepolymerized material, which is a poly(ester of methacrylate), and an ethylenically unsaturated monomer, which is an ester of methacrylate, and (*b*) permitting said fluid self-curing material to cure in situ at a temperature between 59° and 120° F. to form a rigid cured material which conforms to the shape of the affected portion of the body and which has essentially the same volume in the pre-cured state as in the cured state, there being no gas given off during the curing.

2. The process of claim **1** wherein said prosthesis enclosure is first placed in a shoe, wherein said affected part of the body is the metatarsal arch of a foot, and wherein said prosthesis enclosure is placed on the affected portion of said body by placing said foot in said shoe.

3. The process of claim **2** wherein pressure is placed on said fluid self-curing material before it completely cures so that said fluid self-curing material takes the shape of said metatarsal arch.

4. The process of claim **2** wherein said fluid self-curing material is comprised of poly(methyl methacrylate), monomeric methyl methacrylate and acetyl peroxide.

5. The process of claim **2** wherein said prosthesis enclosure is a sealed envelope, with at least its top surface being elastic, wherein said fluid self-curing material is placed in said prosthesis enclosure by piercing a side of said prosthesis enclosure with an elongated, hollow tube device and force injecting said fluid self-curing material through said elongated, hollow tube device into said prosthesis enclosure, and wherein said hollow tube device is removed from said fluid self-curing prosthesis enclosure and said side of said prosthesis enclosure is rapidaly sealed.

6. The process of claim **5** wherein said region of said side of said prosthesis enclosure which is pierced by said hollow tube device is self-curing.

7. The process of claim **3** wherein said prosthesis enclosure is a rigid insert that is placed on or affixed to the insole of said shoe, said insert comprising a flat plate that extends across the width of said insole and extends lengthwise at least across the metatarsal arch of said foot, and a low side wall on the side away from said metatarsal arch which completely covers said arch

when said foot is inserted in said shoe, said foot serving as the top of said prosthesis enclosure, wherein said fluid self-curing material is placed in said prosthesis enclosure by means of a tube inserted between said high side wall and said foot, and wherein said tube is rapidly removed after said fluid self-curing material is placed in said prosthesis enclosure.

8. The process of claim **2** wherein a cast is placed over said prosthesis enclosure before said fluid self-curing material is placed in said prosthesis enclosure.

9. The prosthesis for supporting or restraining a part of the body which comprises a prosthesis enclosure and a rigid, cured non-foamed material, within the prosthesis enclosure, with conforms to the desired shape and which has essentially the same volume in the cured state as it had in the pre-cured state, said rigid, cured, non-foamed material comprising a prepolymerized material, which is a poly(ester of methacrylate), cross-linked by an ethylenically unsaturated monomer, which is an ester of methacrylate, said rigid, cured non-foamed material having been cured at a temperature between 59° and 120° F.

10. The prosthesis of claim **9** wherein said prosthesis enclosure is located between said affected part of the body and a cast.

11. The prosthesis of claim **10** wherein said prosthesis enclosure is located on the insole of a shoe where the metatarsal arch of a foot is located.

12. The prosthesis of claim **11** wherein said prosthesis enclosure is a sealed enclosure.

13. The prosthesis of claim **12** wherein said prosthesis enclosure is a rigid insert that is placed on or affixed to said insole of said shoe, said insert comprising a flat plate that extends lengthwise across the width of said insole and extends lengthwise at least across the metatarsol arch of said foot, and a low side wall on the side away from said metatarsal arch which completely covers said arch when said foot is inserted in said shoe, said foot serving as the top of said prosthesis enclosure.

14. The prosthesis of claim **13** wherein said prosthesis enclosure is comprised of aluminum.

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