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 [21] Appl. No. **39,754**
 [22] Filed **May 22, 1970**
 [45] Patented **Dec. 28, 1971**
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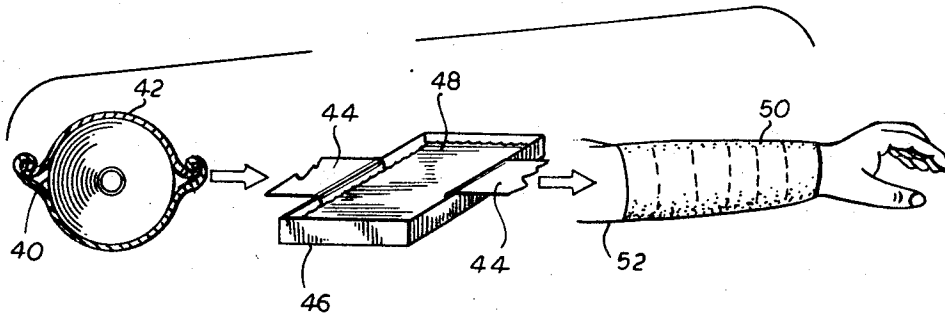
[54] **ORTHOPEDIC BANDAGE**
25 Claims, 2 Drawing Figs.

[52] U.S. Cl. **128/90**
 [51] Int. Cl. **A61I 15/07**
 [50] Field of Search 128/90,
 155, 89; 260/89.7 R

[56] **References Cited**
UNITED STATES PATENTS

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2,969,791	1/1961	Ekenstam et al.	128/90
3,027,336	3/1962	Gotz et al.	128/90 X

ABSTRACT: This orthopedic bandage for immobilizing or supporting portions of the body comprises a flexible carrier such as cotton gauze supporting a solid, water-soluble vinyl monomer selected from the group consisting of diacetone acrylamide and N-isopropyl acrylamide and mixtures thereof. Other monomers and fillers including polymeric and reactive substances may optionally be added to achieve particular properties or results. The bandage is preferably prepared for use by dipping in water in the presence of a catalyst for initiating polymerization of the vinyl monomer and then wrapping the body portion to be immobilized. In the preferred practice the initiator is a part of the bandage and may either be mixed with the monomer or coated on the surface of the bandage.



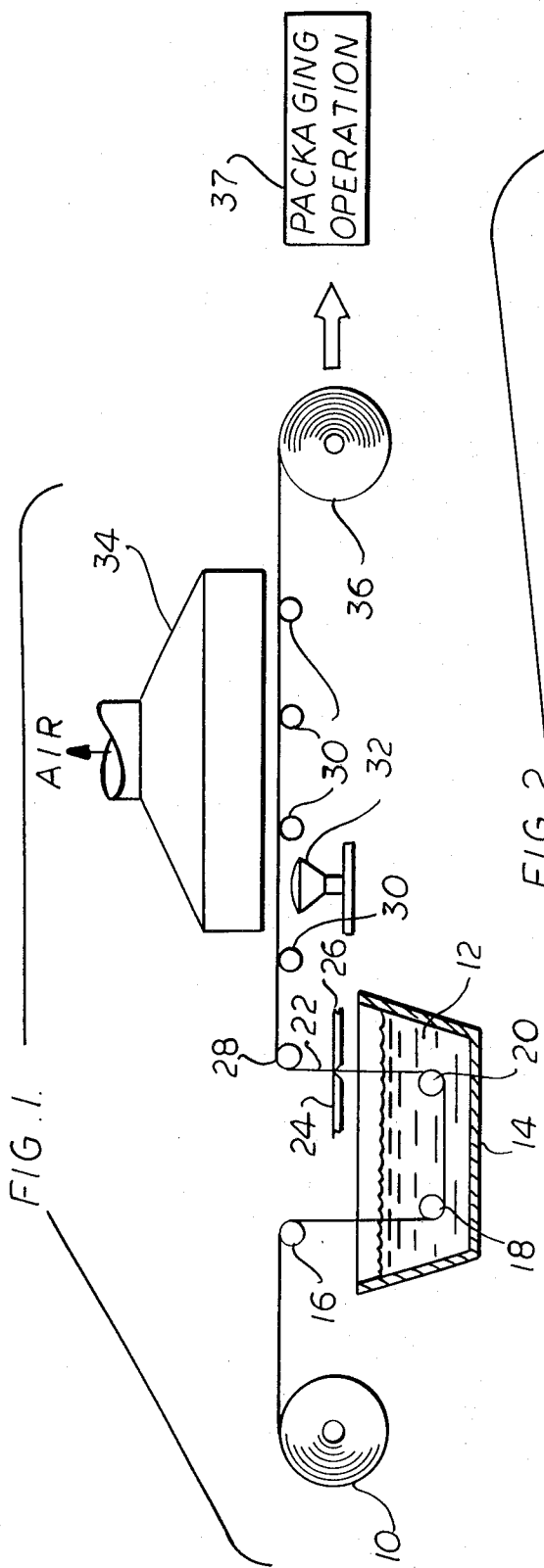
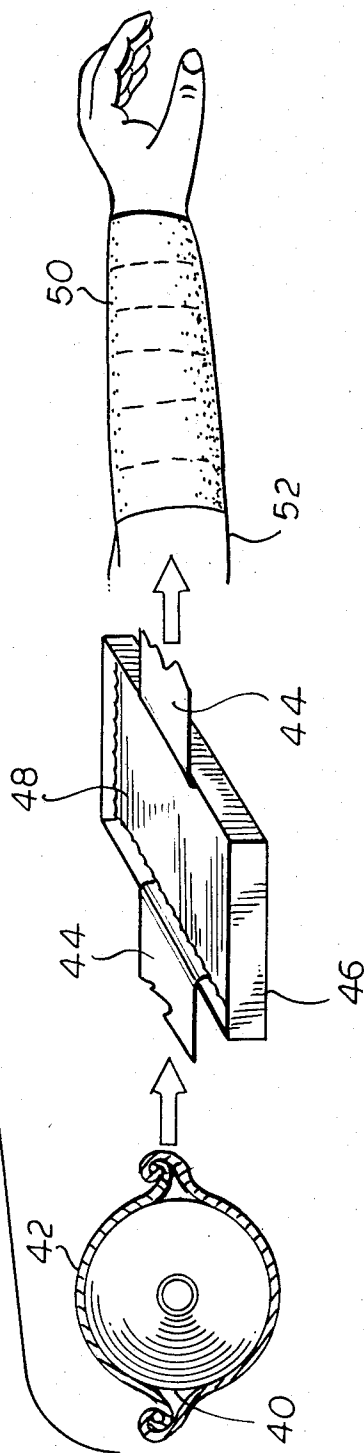


FIG. 1.

FIG. 2.



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ORTHOPEDIC BANDAGE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to the field of orthopedic bandages which are used to form casts for immobilizing and supporting parts of the body such as fractured limbs to permit undisturbed healing. More specifically, it relates to an improved polymeric orthopedic bandage which can be prepared and applied using conventional techniques associated with well-known plaster of Paris casts but has a number of improvements thereover including reduced weight, and greater penetrability by X-ray.

While the present invention is described herein with particular reference to orthopedic bandages for immobilizing portions of the body, it should be understood that the invention is not limited thereto. It can be employed to form hard casts for a variety of uses, particularly where various desirable attributes of a polymeric cast can be advantageously employed, as will be apparent to those skilled in the art.

2. Description of the Prior Art

Plaster of Paris on fabric or gauze bandage has been used almost exclusively in the preparation of surgical casts designed to immobilize and support portions of the body, e.g., a leg, arm, wrist, neck, and the like. Plaster of Paris is inexpensive, convenient and ready to use after simply dipping in water. Moreover, practically all physicians, particularly orthopedic specialists, have long worked with the plaster of Paris medium and are very familiar with its application. Once having mastered the art of working with plaster of Paris, they are reluctant to learn the different techniques associated with other media.

Notwithstanding, plaster of Paris has certain shortcomings. It is relatively heavy and can be damaged by wetting with water. It is also substantially opaque to X-rays, thus sometimes requiring that a cast be removed to ascertain, for example, whether a fracture has satisfactorily healed.

Past efforts to find substitutes for all or a portion of the plaster of Paris in orthopedic casts have been largely unsuccessful, in part because they required the mastering of new techniques and were less convenient to use and suffered from other shortcomings. For example, some substitute casts were substantially impervious to transmission of water vapor and thus perspiration. As another example the use of thermoplastic sheets have been unacceptable because molding temperatures are too high. If an insulating medium is introduced between the thermoplastic material and the skin, the ability to mold or shape the thermoplastic material satisfactorily to the part to be immobilized is compromised.

Previous attempts to use resin structures have also proved largely unsuccessful. For example, the technique disclosed in U.S. Pat. No. 3,027,336, involves the application of the resin in the form of a paste which is inconvenient to prepare and represents a wide departure from the simple and convenient water-dipping technique associated with plaster of Paris, which is so widely accepted and popular. Moreover, it requires the presence of a pore-forming agent to achieve porosity. Similarly, the technique of U.S. Pat. No. 3,089,486, involves the inconvenient impregnation of a polymer-imbued bandage with a liquid, curable monomer component immediately before or after the bandage is placed on the body member.

It is therefore a general object of the present invention to provide an orthopedic bandage which can be applied in substantially the same manner as plaster of Paris casts and yet avoids many of the disadvantages associated therewith, including opaqueness to X-ray and poor water resistance. It is another general object to provide a plastic orthopedic cast which avoids many of the shortcomings of prior art plastic casts, including low water vapor transmission.

It is a more specific object to provide an improved orthopedic bandage from a polymerizable monomer which can be activated by simply immersing the same in an aqueous

medium. It is another object to provide a plastic-based orthopedic bandage from a water-soluble polymerizable monomer which is solid at room temperature and substantially nonirritating in both the monomeric and polymeric forms. It is another object to provide a plastic-containing orthopedic cast which doesn't heat up excessively when curing the same. Still another object is to provide a plastic component for orthopedic casts which is polymerizable under conditions normally encountered by doctors in applying all-plaster casts.

These and other objects of the present invention will become apparent as a detailed description proceeds.

SUMMARY OF THE INVENTION

These objects are achieved by an orthopedic bandage comprising a flexible carrier supporting a cast-forming composition comprising a solid, water-soluble vinyl monomer selected from the group consisting of diacetone acrylamide, N-isopropyl acrylamide, and mixtures thereof. As described in detail hereinafter, to this cast-forming composition may optionally be added certain other monomers or comonomers which are solid at room temperature and nonirritating to the skin and certain fillers, including certain polymeric fillers and water-insoluble insoluble inorganic salts.

The orthopedic bandage so formulated is prepared for use by contacting it with an aqueous medium, preferably hot tap-water, in the presence of catalytic amounts of a polymerization initiator or catalyst whereby the vinyl monomer is polymerized. The polymerization catalyst may be added to the aqueous medium itself, or it may be incorporated into the cast-forming composition. In the latter case, the bandage must be kept dry and out of contact with moisture-laden air. Because two-ingredient catalyst systems are normally employed, one catalytic component may be incorporated in the cast-forming composition and the other catalytic component may be added to the water at the time of dipping, thus minimizing the sensitivity of the composition to water or moisture-laden air.

If the catalyst is incorporated in its entirety in the cast-forming composition, as preferred, the physician need only dip the bandage in water in order to initiate polymerization and prepare the bandage for use. This simple procedure substantially duplicates, of course, the conventional techniques employed in connection with plaster of Paris casts. If the entire catalyst is not incorporated in the cast-forming composition, the physician need only add any missing catalytic component to the water in which the bandage is immersed. Further details of the invention are set forth in the following subsections.

THE FLEXIBLE CARRIER

The flexible carrier may be any suitable support capable of carrying the vinyl monomer prior to the polymerization thereof and otherwise compatible to its intended use, the particular carrier per se not being part of the present invention. It should preferably be somewhat stretchable, conformable and inexpensive. In general, the same flexible carriers employed in connection with plaster of Paris casts may be used in the present invention.

Preferred carriers include open-mesh fabrics such as cotton gauze, cotton crinoline and other natural and synthetic bandage materials well known to those skilled in the art. For example, the carrier may be a cotton gauze having 10 to 50 warp and 10-50 weft threads to the square inch, some or all of the threads optionally being resilient or elastic.

The carrier may either be woven or nonwoven and may also be manufactured in whole or part from plastic or glass fibers. The plastics may include, for example, polyethylene, polypropylene and various polyester or polyamide fibers, e.g., Dacron, nylon and the like. The carrier may also be prepared from porous foams such as polyester and polyether polyurethane foams. Other materials will be apparent to those skilled in the art in the light of the present disclosure.

The Water-Soluble Solid Monomer

Because it is desired that the orthopedic bandage of the present invention be a dry bandage, the vinyl monomer employed therein must be solid at room temperature. In addition, since the bandage is to be prepared for use by simply dipping in aqueous medium, polymerization of the monomer and the catalyst system for initiating the same must lend itself to activation by contact with water. Still further, the monomer must be substantially nonirritating to the skin, both in a monomeric and polymeric form.

These stringent requirements are met by diacetone acrylamide and N-isopropyl acrylamide and mixtures thereof. Diacetone acrylamide is preferred at present because of its lower cost. Casts made, in accordance with the present invention, of polymers of diacetone acrylamide are also porous and thus will transmit perspiration, a distinct advantage in the cast field, as patients will readily testify.

A more precise chemical identification of the diacetone acrylamide employed in the practice of the present invention is N-(1,1-dimethyl-3-oxobutyl-acrylamide). It can be purchased commercially and is presently available, for example, from the Lubrizol Corporation, Wickliffe, Ohio, a corporation of Ohio. In this connection, see, for example, U. S. Pat. No. 3,458,478, issued July 29, 1969, and assigned to The Lubrizol Corporation.

The amount of vinyl monomer of the flexible support may approximate levels employed in plaster of Paris orthopedic bandages. The vinyl monomer may be present in the amounts of about 50 to 800 percent of the weight of the support, typically about 200 to 500 percent. Techniques for controlling the amount of monomer are briefly discussed hereinafter in connection with methods of manufacture and the solvents used therein.

The Polymerization Initiator

A conventional redox initiator system used in emulsion polymerization may be used to catalyze polymerization of the vinyl monomer and hardening of the bandage. These initiators are mixtures of oxidizing and reducing agents generally in the proportions of about 1 to 1 by weight, which react substantially immediately with each other when dissolved in water. Accordingly, both cannot be mixed in aqueous solution until polymerization is to be initiated.

Examples of oxidizing agents are ammonium persulfate, potassium persulfate, hydrogen peroxide, t-butyl hydroperoxide, ferric chloride, hydroxylamine, cobalt (III) chloride, and potassium permanganate. Examples of reducing agents are ferrous sulfate, sodium sulfite, sodium dithionite, ferrous chloride, sodium formaldehyde sulfoxylate, oxalic acid, cobalt (II) chloride, and hydrazine. A catalyst concentration of about 0.5 to 5 percent by weight, based on water, is preferred although higher concentrations, e.g., about 5 to 10 percent, may also be used. Although the oxidizing and reducing agents, making up the initiator system are generally used in a weight ratio of 1 parts oxidizing agent to 1 part reducing agent, this ratio can be varied substantially with effective results still being obtained, for example, with 1 part of either the oxidizing agent or the reducing agent being present with 9 parts of the other.

Both the oxidizing and reducing agents are necessary for polymerization. Both initiators may be added to the water before dipping, or one of the two may be incorporated in the bandage at the time of its manufacture and the other added to the dipping water.

Alternatively, catalytic amounts of both initiators may be incorporated in the bandage at the time of manufacture. Thus, the physician need only dip the bandage in water to prepare it for use. A specific example of a preferred catalyst system employed in this embodiment is ammonium persulfate and sodium sulfite. As already indicated, with both catalysts present, precautions should be taken to avoid contact with water- or

moisture-laden air. As aqueous solutions of initiator tend to become acidic on standing, in the preferred practice a nontoxic, nonirritating buffer, such as sodium bicarbonate, sodium citrate, sodium acetate, disodium phosphate or the like, is added to avoid possible later irritation resulting from such acidification. Thus, a preferred accelerator is a three-part system containing, for example, potassium persulfate, sodium sulfite and sodium bicarbonate in approximately equal proportions by weight.

The temperature of the dipping solution has a profound effect on the hardness of the final cast. The hotter the water, the faster hardening will occur. Water at 120°-130° F. is recommended. Water below 110° F. should preferably not be used, since polymerization of the monomer in the bandage after dipping may be inhibited. Temperatures of 120°-140° F. are readily available in hot tapwater.

Other Ingredients

Other ingredients may also be incorporated into the bandage to act as monomeric supplements, binders, fillers, polymerization rate controllers, and the like. For example, it has been found advantageous to add N-t-butylacrylamide along with the diacetone acrylamide or N-isopropyl acrylamide as a reactive monomer. N-t-butylacrylamide is not soluble in water and cannot be used in the water system by itself but only in conjunction with diacetone acrylamide or N-isopropyl acrylamide.

Other solid monomers or comonomers may also be added, e.g., the following nontoxic derivatives of acrylic and methacrylic acid:

Inorganic Salts (Sodium, Calcium, etc.)

4,4'-Isopropylidene-diphenol esters

N-Vinylsuccinimide

N-Vinylphthalimide

P-Vinyl Benzamide

Vinyl Naphthalene

N-Vinylcarbazole

The common vinyl monomers (styrene, methyl methacrylate, methyl acrylate, vinyl acetate, vinyl chloride, ethylene, and acrylamide) are excluded from consideration since they are either not solid at room temperature or they are known to be capable of irritating the skin.

To bind the diacetone acrylamide and N-isopropyl acrylamide (and any other monomers or comonomers) to the flexible carrier, and to prevent their loss in the dipping water upon contact therewith, a thin film of adhesive may be added to the ingredients at the time of manufacturing the bandage. For example, a binder may be formed by evaporation of a latex, e.g., Rhoplex B-15, a latex product of Rohm and Haas Company, and UCAR-TCX-8960, a latex product of Union Carbide Corporation. Care should be taken, however, to avoid contact with water in the presence of initiator. Accordingly, where a latex is used as the binder system, the water should be removed before imparting the initiator.

In addition to, or in place of, the binder, various types of fillers may be used, including polymeric fillers and water-insoluble inorganic salts. Fillers reduce the amount of more costly monomer required. They also control the rate of water entering the bandage and thus the rate of reaction. By thus slowing the rate of reaction and increasing the bulk, the temperature rise from the polymerization reaction is reduced and moderated, minimizing any discomfort to the patient.

Almost any nontoxic, nonirritating polymer can be used as a filler. Preferably, they should coat out as a binder for the vinyl monomer, i.e., the diacetone acrylamide or N-isopropyl acrylamide. The binding action holds the monomer on the flexible carrier and minimizes undesired leaching into the dipping water. As examples of fillers one may use substantially water-insoluble fillers such as cellulose acetate, poly(methyl methacrylate), poly(diallyl phthalate), polycaprolactone, copolymer of ethylene and maleic anhydride, and copolymers of styrene and maleic anhydride; as water-soluble fillers one

may use, for example, poly(ethylene oxide), methyl cellulose, carboxymethyl cellulose, hydroxy ethyl cellulose and polyacrylamide. The water-soluble fillers are generally preferred as they give more rapid wetting times.

Inorganic fillers may be added to improve the ease of wrapping of the bandage. In particular, they render the bandage less sticky and, as aforementioned, moderate any temperature rise. Calcium sulfate or calcium carbonate are preferred, but other commercial fillers (e.g., bentonite, silica, etc.) can also be used. The presence of such inorganic fillers is not necessary, whereas the presence of a polymer filler is considered quite desirably.

When calcium sulfate hemihydrate, e.g., plaster of Paris, is employed as a filler, a hybrid system results. The monomer polymerizes and the plaster of Paris takes up water to form calcium sulfate dihydrate. Advantageously, neither the rate of polymerization of the monomer or hydration time of the plaster of Paris is unduly modified by the presence of the other reactive component. The presence of the polymer renders the cast far less opaque to X-ray than an all-plaster cast, and otherwise imparts the advantageous features of the polymer.

Of the total solids on the flexible carrier, the monomer or comonomer components comprise between about 30 and 100 percent by weight of the total and the filler comprises between about 0 to 70 percent. The preferred ranges are about 50 to 80 percent monomer and 20 to 50 percent filler.

The monomer component itself should comprise at least about 30 percent by weight, based on total monomer, of diacetone acrylamide or N-isopropyl acrylamide or mixtures thereof, preferably about 40 to 80 percent, the balance being other monomeric or comonomeric components hereinabove set forth, e.g., N-t-butylacrylamide. Accordingly, at least about 9 percent of the total solids must consist of diacetone acrylamide or N-isopropyl acrylamide or mixtures thereof.

The filler component itself may contain anywhere between 0 and 100 percent by weight, based on total filler, of polymer, the remainder being inorganic salt. The preferred range of polymer content in the filler is about 50 to 100 percent.

Further information on ingredients and proportions thereof are set forth hereinafter in the description of methods of manufacture and in the specific examples.

Packaging

When both initiators are incorporated in the cast-forming composition at the time of its manufacture, the orthopedic bandage must be maintained in a dry state until the time of use, as previously discussed. Accordingly, in order to prevent premature polymerization of the vinyl monomer, the bandage is packaged, preferably in roll form, in a moisture-resistant container which may be readily opened at the time of use.

In a preferred embodiment wherein the initiators are incorporated in the orthopedic bandage, the bandage is sealed in an aluminum foil package which may be readily torn open for use. Various alternative containers may also be employed, as those skilled in the art will readily recognize.

Methods Of Manufacture and the Solvent Employed Therein

The bandage of the present invention may be manufactured by various techniques, as is exemplified by the methods of preparation of preferred forms thereof. In one specific embodiment, a cotton gauze bandage is impregnated with diacetone acrylamide, N-t-butylacrylamide, cellulose acetate, ammonium persulfate and sodium sulfite, the latter two ingredients being the initiators. As aforementioned, a buffer such as sodium bicarbonate is preferably included also. The impregnation is accomplished by dissolving the ingredients in a suitable solvent. The bandage is passed through the solution and then between metering rolls or knives to achieve the desired level of impregnation. The solvent is evaporated therefrom by conventional techniques, e.g., heating, blowing air thereover, and the like.

The resulting orthopedic bandage is then sealed in an aluminum foil package to avoid contact with moisture-laden air. At the time of use the package is torn open, and the bandage is momentarily dipped in hot tapwater then lightly squeezed after removal. It is immediately wrapped around the body portion to be immobilized in a plurality of layers and allowed to set, becoming slightly warm (e.g., about 110° F.) for about 15 minutes in the process. After cooling to about room temperature (another 10-30 minutes or so), the cast has hardened sufficiently for the desired immobilization.

When initially incorporating the diacetone acrylamide or N-isopropyl acrylamide into the flexible carrier, a variety of solvents may be employed, depending upon the presence and nature of other ingredients and whether the catalyst system is included. The solvent must be easily evaporated below the maximum temperature to which the monomer can be warmed without polymerizing. For diacetone acrylamide, this temperature is its melting point, i.e., 57° C. Both methylene chloride (boiling point of 40° C.) and acetone (boiling point of 56° C.) are preferred solvents. Other solvents that could be used are water, methyl acetate, ethyl acetate, diethyl ether, chloroform, carbon tetrachloride, tetrahydrofuran, benzene, and toluene. Since the rate of evaporation of a solvent can be speeded by blowing air across the bandage, solvents with boiling points above 57° C. may be used as well.

The choice of concentration of monomer and polymer in the solvent is determined by the viscosity of the final solution. The viscosity is in turn determined by the molecular weight range of polymer used; the greater the molecular weight, the greater the viscosity. Highly viscous solutions are undesirable, since the final bandage coating is thick, and the bandage is hard to wrap. Very thin solutions yield very thin coatings of the bandage with an insufficient supply of deposited monomer.

The cast-forming composition may also be incorporated into the support without the use of a solvent, as will become apparent from the specific examples hereinafter set forth. The use of a solvent is, however, the preferred technique at present.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more clearly understood from the following detailed description of specific embodiments, read in conjunction with accompanying drawings, wherein:

FIG. 1 is a schematic illustrated production of a preferred embodiment of the orthopedic bandage of the present invention; and

FIG. 2 is a schematic illustrating the simple steps of using the bandage produced in FIG. 1 to form a cast to immobilize a human forearm.

DESCRIPTION OF PREFERRED EMBODIMENT

Referring to Fig. 1, the starting material is a roll of open-mesh cotton gauze bandage 10 which is passed through impregnating solution 12 in vessel 14 by means of direction changing rollers 16, 18 and 20. Impregnating solution 12 comprises diacetone acrylamide, N-t-butylacrylamide, cellulose acetate, ammonium persulfate and sodium sulfite in an acetone solvent, illustrative proportions being indicated in example 6 set forth hereinafter. If a buffer is included, e.g., sodium bicarbonate, it is preferably present in the same weight proportion as the ammonium persulfate or sodium sulfite.

Leaving impregnating solution 12, the impregnated web 22 passes between metering knives 24 and 26 or equivalent metering rolls (not shown), which control the level of solution on the web. Web 22 then passes around direction changing roller 28 and across a series of supporting rollers 30, where it is subjected to slight warming from a row of infrared lamps 32 and rapid air currents exhausted via exhaust fan hood 34. As a result, the acetone solvent is driven off, leaving a dry bandage containing the cast-forming composition which is accumulated as orthopedic bandage roll 36.

Since the dry bandage contains polymerizable monomers as well as a catalyst system for initiating polymerization in the presence of water, the dry bandage is packed in a moistureproof sealed container in zone 37. An inexpensive and effective container for such purposes may be an aluminum foil package which can be readily torn open at the time of use.

In FIG. 2, a packaged orthopedic bandage of the present invention is illustrated as bandage roll 40 in aluminum foil package 42 which is hermetically sealed. At the time of use, package 42 is torn open and the entire roll 40 or a desired length 44 thereof is dipped in a vessel 46 containing hot tap-water 48 (e.g., about 120–130° F.). Following dipping the bandage is lightly squeezed to remove excess water and then promptly applied to the body portion to be immobilized, as illustrated by cast 50 on forearm 52.

Because the bandage is conformable and requires no barrier between itself and the skin, it can be closely fitted to the body portion and rapidly built up in a plurality of smooth layers into an integral cast. The cast rapidly cures, with temperatures never reaching excessively painful levels, and becomes hard within less than an hour of its initial application.

The present invention will be more clearly understood from the following specific examples of formulations used in preparing orthopedic bandages, as well as test results obtained when using such orthopedic bandages.

EXAMPLES

Example 1

A paste consisting of 50 parts by weight of diacetone acrylamide and 20 parts by weight of UCAR Latex TCX-8960 was spread with a spatula on a gauze bandage measuring 1 yard long and 3 inches wide. The bandage was hung dried by standing overnight. The dried bandage was rolled and dipped in a solution of 21 parts by weight of ammonium persulfate and 2 parts by weight of sodium sulfite in 100 parts by weight of water. The solution was made up just prior to dipping of the bandage.

The bandage was removed from the solution a few seconds after immersion and wrapped around a 1-inch diameter dowel or pipe covered with aluminum foil. The bandage became sticky, warm, but not hot a few minutes after wrapping. Fifteen minutes after the wrapping the bandage was no longer sticky. After an hour the cast was hard and cool. The crushing strength of the cast measured the next day was 250 pounds as shown on a Dillon Dynamometer.

Example 2

A paste consisting of 400 parts by weight of plaster of Paris, 100 parts by weight of diacetone acrylamide, 220 parts by weight of water, 4 parts by weight of ammonium persulfate, and 4 parts by weight of sodium sulfite was spread on a cotton gauze bandage 1 yard long and 3 inches wide. The bandage was wrapped around a wooden stick, 1 inch in diameter, bearing an aluminum foil cover with a thermometer placed between foil and stick.

The bandage hardened 9 minutes after wrapping. The maximum temperature recorded on the thermometer at any time was 78° F. After 45 minutes the cast was removed from the stick. The cast could barely be deformed by hand pressure at this time. The maximum strength of the cast, recorded 6 days later, was 285 pounds as recorded on a Dillon Dynamometer.

Example 3

A gauze bandage, 10 yards by 4 inches, is impregnated with a solution of 150 parts by weight of diacetone acrylamide, 75 parts by weight of Plexiglas VS-100 poly (methyl methacrylate) (Rohm and Haas Company, Philadelphia, Pennsylvania), and 25 parts by weight of Hydrocal plaster of Paris (Unites States Gypsum Company) in 400 parts by weight of methylene chloride. The bandage is dried in circulating air at 100° F., rolled up and inserted in a sealable container.

A bandage 5 yards by 4 inches cut from the above coated bandage is dipped in a solution of 8 parts by weight of sodium

sulfite and 8 parts by weight of ammonium persulfate in 300 parts by weight of water of about 115° F. The bandage is removed immediately from the solution, squeezed lightly, and wrapped around a patient's limb. The bandage becomes warm, maintaining a temperature of 110° F. for 15 minutes and then cooling to room temperature, at which point the cast is hard to the touch.

A similar bandage can be prepared by substituting N-isopropyl acrylamide for diacetone acrylamide and using the same reagents and parts by weight as in the above example. A similar bandage can also be prepared by substituting cellulose acetate for the poly (methyl methacrylate) and omitting the plaster of Paris completely.

Example 4

Two bandages (5 yards by 4 inches) weighing about 20 parts each are coated with a solution prepared from 150 parts by weight of diacetone acrylamide, 75 parts by weight of Plexiglas VS-100 poly (methyl methacrylate) and 75 parts by weight of Hydrocal plaster of Paris in 470 parts by weight of methylene chloride. Upon evaporation of the solvent, 88 parts of coating are deposited on each bandage.

These orthopedic bandages are activated by dipping in hot tapwater containing catalytic quantities of an initiator, e.g., ammonium persulfate and sodium sulfite. The activated bandage is then promptly applied to a limb to form a plastic cast.

Example 5

Cylindrical casts were prepared from orthopedic bandages similar to those of examples 3 and 4. A cylindrical cast 4 inches long with a 2-inch inside diameter, weighing about 0.31 pounds showed a crushing strength on a Dillon Dynamometer of about 145 pounds 1 hour after wrapping, about 250 pounds 24 hours after wrapping, and about 450 pounds 1 week after wrapping. The strength-to-weight ratio varied from about 470, 1 hour after wrapping, to about 1,450, 1 week after wrapping.

The transmission of perspiration is a requirement in any proposed orthopedic cast. Flat, rectangular casts were, therefore, prepared from orthopedic bandages similar to those of examples 3 and 4 for measurement of moisture-vapor-transmission. The results obtained with casts having 5, 10 and 23 plies are as follows:

No. Of plies	Vapor Transmission of Water	
	Grams of water per 100 in. ² per 24 hours	
5		31
10		9
23		8

The ability of these solid, apparently opaque plastic casts, to transmit water vapor is considered remarkable. Most polymers would transmit no water at all.

Example 6

An impregnating solution was prepared from 30 parts by weight of E-398-10 cellulose acetate (Eastman Chemical Products, Inc.), 113 parts by weight of diacetone acrylamide, 37 parts by weight of N-t-butylacrylamide, 20 parts by weight of ammonium persulfate and 20 parts by weight of sodium sulfite in 400 parts of acetone. Two cotton gauze bandages, each measuring 2 yards by 4 inches and weighing about 10 parts by weight, were impregnated with the solution and dried. Each of the resulting orthopedic bandages weighed about 80 parts, thus indicating a solids pickup from the solution of about 70 parts by weight.

The bandages were dipped in 300 milliliters of water at about 140° F. and wrapped around a core. During polymerization temperatures reached about 140° F. at the core.

Example 7

Patches of orthopedic bandages containing diacetone acrylamide and prepared as indicated in examples 3, 4 and 6 where no buffer was used with the activator, were taped on

human males and females in a routine testing procedure for the skin irritation potential of the new cast. With the exception of two possible allergenic responses to the bandages, no irritation was evident.

This tests repeated on the two allergenic patients, however, this time using a buffered accelerator solution, the buffer used being sodium bicarbonate. No irritation was observed with the one patient. The other showed some irritation, but when tested was found to show the same degree of irritation to sodium bicarbonate alone.

Animal tests were performed by injecting mice and guinea pigs with extracts of polymerized bandage prepared in accordance with the present invention. No irritation was observed in mice, while a positive sensitizing reaction was observed in guinea pigs, which was considered to be of little significance. No irritation was observed after application of unpolymerized bandage on strip wounds on rabbits. The bandages is, therefore, considered safe for use on humans.

From the above description, it is apparent that the objects of the present invention have been achieved. While only certain embodiments have been illustrated, many alternative modifications will be apparent from the above description to those skilled in the art. These and other alternatives are considered within the spirit and scope of the present invention and coverage thereof is intended by the claims of any patents based on this application and any continuations or divisions thereof.

Having described the invention, what is claimed is:

1. An orthopedic bandage comprising a flexible carrier having adhered thereto a dry cast-forming composition comprising at least about 9 percent by weight of a solid, water-soluble vinyl monomer selected from the group consisting of diacetone acrylamide, N-isopropyl acrylamide, and mixtures thereof.

2. The orthopedic bandage of claim 1 wherein said cast-forming composition includes about 20 to 60 percent by weight, based on total monomer, of N-t-butylacrylamide.

3. The orthopedic bandage of claim 1 wherein said cast-forming composition includes sufficient polymerization initiator to polymerize said water-soluble vinyl monomer in the presence of water.

4. The orthopedic bandage of claim 3 wherein said polymerization initiator comprises a mixture of oxidizing and reducing agents.

5. The orthopedic bandage of claim 3 wherein said polymerization initiator includes a buffer component to control acidity.

6. The orthopedic bandage of claim 3 wherein said polymerization initiator comprises ammonium persulfate and ferrous sulfate.

7. The orthopedic bandage of claim 3 wherein said polymerization initiator comprises ammonium persulfate and sodium sulfite.

8. The orthopedic bandage of claim 7 wherein said polymerization initiator includes a buffering quantity of sodium bicarbonate.

9. The orthopedic bandage of claim 3, including an encompassing, substantially moistureproof container therefor.

10. The orthopedic bandage of claim 1 wherein said cast-forming composition includes about 20 to 60 percent by weight, based on total monomer, of a nonirritating, solid

monomeric derivative of acrylic and methacrylic acid.

11. The orthopedic bandage of claim 1 wherein said cast-forming composition includes up to about 70 percent by weight, based on said composition, of a solid filler.

12. The orthopedic bandage of claim 11 wherein said solid filler comprises a polymeric filler.

13. The orthopedic bandage of claim 11 wherein said solid filler is a water-soluble polymeric filler selected from the group consisting of poly (ethylene oxide), methyl cellulose, carboxymethyl cellulose, hydroxy ethyl cellulose polyacrylamide or mixtures thereof.

14. The orthopedic bandage of claim 11 wherein said solid filler is a water-insoluble polymeric filler selected from the group consisting of cellulose acetate, poly (methyl methacrylate), poly (diallyl phthalate), polycaprolactone, copolymers of ethylene and maleic anhydride, copolymers of styrene and maleic anhydride or mixtures thereof.

15. The orthopedic bandage of claim 12 wherein said polymeric filler comprises cellulose acetate.

16. The orthopedic bandage of claim 12 wherein said polymer filler comprises methyl methacrylate polymer.

17. The orthopedic bandage of claim 11 wherein said filler comprises a water-insoluble inorganic salt.

18. The orthopedic bandage of claim 17 wherein said water-insoluble inorganic salt comprises calcium sulfate.

19. The orthopedic bandage of claim 17 wherein said water-insoluble inorganic salt comprises calcium carbonate.

20. The orthopedic bandage comprising a flexible fabric carrier having adhered thereto a cast-forming composition comprising about 20 to 64 percent by weight, based on said composition, diacetone acrylamide, about 10 percent to 48 percent by weight, based on said composition, of N-t-butylacrylamide and about 20 to 50 percent by weight, based on said composition, of cellulose acetate.

21. The orthopedic bandage of claim 20 wherein said cast-forming composition includes a catalytic quantity of initiator for polymerizing said diacetone acrylamide.

22. A packaged orthopedic bandage comprising a substantially moistureproof container having enclosed therein a flexible fabric carrier having adhered thereto a dry cast-forming composition comprising at least about 9 percent by weight of diacetone acrylamide and a catalytic quantity of initiator for polymerizing said diacetone acrylamide.

23. The packaged orthopedic bandage of claim 22 wherein said container comprises an aluminum foil package.

24. A method of forming a rigid orthopedic cast for body members comprising the steps of:

- a. providing an orthopedic bandage comprising a flexible fabric carrier supporting a dry, cast-forming composition comprising at least about 9 percent by weight of a solid, water-soluble vinyl monomer selected from the group consisting of diacetone acrylamide, N-isopropyl acrylamide, and mixtures thereof;
- b. immersing said bandage in a aqueous medium in the presence of a polymerization initiator for said vinyl monomer;
- c. wrapping said orthopedic bandage in a plurality of layers around the body member to be immobilized; and
- d. allowing said vinyl monomer to polymerize.

25. The method of claim 24 wherein said polymerization initiator is present on said bandage prior to immersion thereof.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,630,194

Dated December 28, 1971

Inventor(s) Franklin Boardman

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In Column 7, line 37, "21 parts" should read--- 2 parts ----.

In Column 9, line 5, " This tests repeated on the two allergenic patients " should read --- This experiment was repeated on the two allergenic patients ----.

Signed and sealed this 11th day of July 1972.

(SEAL)
Attest:

EDWARD M.FLETCHER, JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents