

PATENT SPECIFICATION

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See Note at end of Specification

(54) IMPROVEMENTS IN AND RELATING TO ORTHOPEDIC DEVICES

12/17/72

(71) We, SOLAR LABORATORIES INC., a corporation organised and existing under the Laws of the State of California, United States of America, of 5140, West 106th Street, Inglewood, California, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to orthopedic devices, especially casts, and methods for their application.

It has been recognized that orthopedic casts for use in the treatment of bone fractures and other conditions requiring immobilization of body members may be advantageously formed from plastics or reinforced plastics materials. By a "body member" there is herein meant any part of a human or animal body which can be immobilized by an external orthopedic device; the body member will in general be a limb such as an arm or leg but could also be, for example, a part of the back or the neck of the human or animal.

The advantages of plastics casts over the more common materials such as plaster of Paris are manifold. In general, a plastics cast is impervious to water, lightweight, characterized by a high strength-to-weight ratio, and substantially transparent to X-rays thus permitting X-ray study of the member after placement in the plastics cast. Previously, however, the use of plastics materials for orthopedic casts has been limited because of the difficulty of applying the plastics material to the body member. The plastics casts have hitherto generally been formed using a plastics impregnated fabric or cloth which is applied to the body member while the plastics material is in a liquid or semi-liquid form.

One proposed method of producing a plastics cast *in situ* utilizes cross-linking

techniques at room temperatures with the use of polyester, acrylic, epoxy, or urethane resin systems, which can be catalyzed by the addition and blending of certain catalytic or copolymer agents. The catalyzed resin may then be used to impregnate the reinforcing fabric. However, the reinforced fabric must be applied to the body member within a few minutes since gelling occurs quickly. The procedure, while practical in certain cases, requires considerable skill and time in proportioning and mixing the ingredients, and then in applying the sticky resin to the reinforcing fabric. The application of the wet mass to the body to form the cast is also difficult and inconvenient. Moreover, many of the resin-forming materials when in the liquid state are toxic. Therefore their use is not practical and, in fact, is unacceptable to the medical practitioner.

Another proposed approach in the application of plastics casts involves the use of pre-catalyzation and the development of a so-called "B" state in resins, where the system is advanced to a condition in which the impregnated fabric has a reasonable shelf life. Upon the application of heat the reaction and polymerization can be made to go to completion. Thus, a fabric impregnated with dry resin which has been advanced to the "B" state can readily be wrapped in place on the body member. However, the amount of heat and the time required with existing resin systems to complete the hardening process makes the system impractical, especially for sentient patients.

Accordingly, it is a principal object of this invention to provide for the application of orthopedic devices, especially casts, formed of lightweight plastics materials without the need for the use of heat or the requirements for wet lay-up techniques.

The present invention provides a method

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for the formation of an orthopedic device which comprises enclosing a body member, as hereinbefore defined, in a fabric impregnated with an ultraviolet radiation-curable organic material, which fabric is substantially free of excess liquid, and curing said material by exposure to ultraviolet irradiation to form a hard device.

It will be appreciated that in many cases the fabric will be impregnated with a liquid resin and that by the term "substantially free of excess liquid" there is simply meant that the fabric does not carry such an amount of liquid that it feels wet and messy.

The method of the present invention is especially applicable to the formation of simple orthopedic casts but may also advantageously be used in the application of other orthopedic devices, for examples, braces.

The present invention also provides a length of bandage material which is impregnated with an ultraviolet radiation-curable organic material and is suitable for use in the method of the invention.

The ultraviolet radiation curable organic material may be applied to the fabric by a variety of techniques. For example, the fabric may be simply dipped in a polymer solution and thereafter permitted to dry prior to being placed on the body member or it may be pre-impregnated and stored in suitable packages or containers before being applied to a body member. The fabric itself may be any fibrous material capable of being impregnated by the polymer. In this respect, the term "impregnate" is used to describe a condition in which the polymer is thoroughly intermingled with and in surrounding relation to the threads or fibres of the fabric and does not necessarily indicate that the plastics material is to any extent absorbed by the fibres themselves. The fabric may be woven or non-woven but will generally have a relatively open, knit structure, and the polymer solution will flow into the spaces between the individual fibres of the fabric and become rigidly bonded to the fabric upon hardening of the polymer material by exposure to ultraviolet radiation. The fabric itself is preferably made of cotton, synthetic fibre, or fibreglass. However, the particular fabric selected will depend upon the particular application.

The present invention is not limited to the use of any specific ultraviolet radiation-curable organic material. The materials have the advantage that no additional chemical catalyst is required, and that the initiation of cure does not depend upon elevated temperature. Thus, many polymers previously unsuitable in the preparation of orthopedic devices are usable in the practice of this invention. While the use of accelerators and/or catalysts is not essen-

tial, these materials may be used in certain formulations in order to speed the curing of the resin upon exposure to ultraviolet radiation. In any event, the ultraviolet radiation-curable resins used in this invention will quickly form a rigid and/or hard, lightweight material at room temperature, thereby avoiding the need for the application of heat thereto and without producing high, body-irritating temperatures.

Suitable ultraviolet radiation-curable organic materials for use in this invention, for example, comprise materials which undergo photocatalytic polymerization, for example, ethylenically unsaturated materials which can be polymerized by photocatalytic initiation. In these materials, the initiation is a first order reaction caused by double bond activation, and any terminal double bonds are progressively activated. In general, the initiation is proportional to the concentration of monomer, and to the square root of light intensity.

The preferred organic materials used in the present invention comprise a monomeric ethylenically unsaturated component capable of dissolving minor amounts of a photoinitiator which is active under ultraviolet light. The use of monomeric substances e.g. styrene alone is however, not generally practical because of low viscosity, high shrinkage upon polymerization, obnoxious odour, and insufficient strength. For these and other reasons a higher polymeric substance such, for example, as a compatible unsaturated polyester resin is combined with the monomer to form a solution, which may be a solid or a viscous liquid.

Suitable ultraviolet radiation-curable organic materials are resins which comprise, for example, an unsaturated polyester, e.g. a non-catalyzed commercial polyester of a non-aniline type (i.e. substantially free of aromatic anilines), together with, as monomer co-reactant, a compatible terminally ethylenically unsaturated monomer, including, for example, compounds containing vinyl, acrylic or allyl radicals such, for example, as styrene, methyl methacrylate and triallyl cyanurate respectively. The monomer is generally used in an amount of from 5 to 50%, by weight of the resin, along with from 0.002% to 5% by weight of the resin of a photoinitiator.

There may especially be mentioned as ultraviolet radiation-curable organic materials (a) a resin comprising a polymethacrylate dissolved in a monomeric methacrylate and containing a photoinitiator and (b) a resin comprising an unsaturated polyester, about 30% by weight of styrene and about 1% by weight of benzoin.

Suitable photochemical initiators, sometimes also referred to in the art as photocatalysts, for use in the ultraviolet curable

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resin systems of the present invention in-
clude, for example, benzoin argo nitriles, for
example, azobisisobutyronitrile, and hydroxy
benzophenones, for example, 2,2' dihydroxy-
5 4,4' dimethoxybenzophenone and 2,4 di-
hydroxybenzophenone. For example, the
addition of benzoin in the amounts as low
as 0.5% to monomeric styrene will not affect
the shelf life appreciably if kept away from
10 light. Upon exposure to moderate intensity
ultraviolet light, however, the rate of poly-
merization is increased to approximately 10
times the rate for styrene containing no
photoinitiator.
15 Other ultraviolet radiation-curable sys-
tems suitable for use in the practice of the
present invention include, for example, the
iodoform-sensitized hardenable colloids dis-
closed in U.S. Patent No. 1,587,274; and the
20 metal carbonyl-sensitized aliphatic diene-
unsaturated long chain oil systems described
in U.S. Patent 1,891,203. The materials con-
taining iodoform or other bactericides have
the additional advantage of providing an
25 antiseptic material on the impregnated
fabric. Many other ultraviolet-curable poly-
mers systems are known and are suitable for
use in the present invention.
30 Any light with high enough energy per
quantum or of short enough wavelength can
initiate polymerization directly. For prac-
tical reasons concerned with readily avail-
able energy sources, and to provide quick
polymerization after the impregnated fabric
35 has been placed on the body member, it is
desirable to use a photochemical initiator
which acts as an absorber, and releases free
radicals under ultraviolet light in the region
of 3600 Angstroms. Convenient spectral
40 sources containing bands of 3600 Angstrom
light energy are mercury vapour discharge
lamps, sunlamps, fluorescent lamps with
special phosphors, and sunlight.
45 The fabric material which is impregnated
with the ultraviolet radiation-curable resin
system may be in the form of a continuous
sheet, or of short or long strips. For ex-
ample, the impregnated fibre may be about
2 inches wide and after impregnation rolled
50 up until it is desired to use the same in
wrapping a body member. In applying the
rolled up material to the body member, the
strip is wrapped around the member in an
advancing over-lapping manner, advancing
55 about one inch per turn. When the member
has been completely wrapped in the im-
pregnated fabric, it is exposed for a short
time of the order of from five minutes to
one-half hour to ultraviolet irradiation.
60 Alternatively, prior to the wrapping of
the member with the impregnated fibre, the
member may be first covered with a
stockinette and/or a plastics wrap such as
polyethylene. Thereafter, when the polymer
65 has been cured, the stockinette and/or the

plastics wrap may be left in place or, more
preferably, slipped out from inside the cast
to leave a cast free of material tending to
permanently entrap moisture against the
70 skin to cause skin infection and/or irritation.
The removal of the sockinette is facilitated
by the presence of an interlayer wrapping
of plastics material to prevent adhesion of
the cast to the sockinette.
75 The invention will now be more par-
ticularly described with reference to the fol-
lowing examples, in which the parts and
percentages being by weight unless otherwise
indicated. Examples 1 to 7 relate to the
preparation and properties of the resins used
80 in the present invention.
Example 1 Resin A
A typical general purpose rigid polyester
was made as follows:
85 An alkyd kettle equipped with heating
means, turbine type agitation, gas sparger
inlet, reflux condenser and temperature con-
trols was charged with
Phthalic Anhydride 35.07 Parts
Propylene Glycol 41.71 Parts 90
and heated at 450°F until an acid number
of 15 was reached. Maleic anhydride 23.22
parts was then added in small increments,
and by cooling a temperature was main-
95 tained at 400°F in the kettle, and held for
4 hours. The temperature was then dropped
to 200°F.
Styrene Monomer 45.74 Parts
Para Tertiary Butyl Catechol 0.13 Parts
were mixed and added to the contents of 100
the kettle with good agitation.
Benzoin 1.0 Part
was then added and dissolved. The con-
tents of the kettle were then cooled and
discharged to a metal container. 105
Example 2 Resin B
A flexible type of polyester was made in
a similar manner to Example 1 comprising
the following:
Phthalic Anhydride 23.65 Part 110
Adipic Acid 5.81 Parts
Maleic Anhydride 19.64 Parts
Diethylene Glycol 50.90 Parts
After the reaction was completed and cooled
115 Triallyl Cyanurate Monomer 46.50 Parts
Hydroquinone 0.04 Parts
were mixed and blended to the charge
Azobisisobutyronitrile 0.5 Parts
was then added and the kettle contents dis-
120 charged to a metal storage container.
Example 3
A commercial polyester Laminic (Trade
Mark) 4123 (American Cyanamide) was
combined with 1% by weight of UV50 Sun-
light catalyst made by U.S. Peroxygen and 125
stored in a dark container.
Example 4
Plaskon (Trade Mark) 942 (Allied
Chemical Co.) a commercial polyester was
combined with 2,4 Dihydroxybenzophenone 130

0.5% and stored in a metal container.

Example 5

- 5 A commercial polyester Polylite (Trade Mark) 31000 (Reichhold Chemical) was blended with 0.5% benzoin dissolved in styrene monomer and stored in a closed container away from light.

Example 6

- 10 A quantity of Resin A as prepared in Example 1, was poured into an open faced, dumbbell shaped, tensile strength, test casting mould, to a depth of 0.125". The light from a mercury arc lamp AH⁴ made by General Electric was allowed to fall on the fluid contents of the mould from a distance of 12". It was observed that within 30 minutes the contents of the mould had solidified due to the ultraviolet radiation from the lamp. A similar test without the mercury light, did not cause polymerization even after 24 hours.

Test data on the tensile specimens so cast showed:

- | | | |
|----|--------------------|------------|
| | Tensile strength | 6,500 psi |
| 25 | Flexural strength | 16,000 psi |
| | Percent elongation | 1.5 |

Example 7

- 30 A 50/50 blend was made of Resin A Example 1, and Resin B Example 2 and cured by the light of a mercury arc lamp in tensile specimen moulds. The following data was obtained from the castings:

- | | | |
|----|--------------------|-----------|
| | Tensile strength | 4,100 psi |
| | Flexural strength | 8,000 psi |
| 35 | Percent elongation | 6.8 |

Example 8

- 40 A strip of 5.73 ounce fibreglass cloth 57" x 30" x 0.0055" thick was saturated with Resin A and passed through rolls until excess resin was removed. The resin pick-up was 40% by weight. The impregnated cloth was wrapped around a collapsible mandrel and exposed to the light of a 250 watt General Electric UA-2 ultraviolet lamp from a distance of 12". After twenty minutes the lamp was removed and the resin impregnated glass examined. It was found to be a rigid self-supporting structure, and without noticable heat content. No tackiness was apparent and upon removal of the mandrel the tube was capable of supporting considerable weight in spite of the light weight.

Example 9

- 55 A 4 ounce woven fibre glass tape 2" wide was impregnated with a solution of the resin of Example 3 in acetone. The ribbon was passed through rolls and through a hot air bath to remove the solvent. By measurement the resin concentration in the cloth was 34%. The slightly tacky tape was then rolled around a cylindrical core with polyethylene tape interposed between each layer as a separation. The wound core was then placed in an impervious plastic bag and

stored at 30°F for two months. The tape was then allowed to come to room temperature and wound spirally on a flexible mandrel.

70 Exposure to ultraviolet light from a sun lamp at a distance of 8" produced a rigid structure which was conformed to the flexible shape. Examination showed the plastic shape to be rigid, tack free, lightweight, and very strong.

Example 10

80 A roll of 1½" wide 0.005" pliable nylon bias tape was unrolled and continuously passed through a tank and around submerged rollers. The tank was filled with a 85% solution of the resin system in Example 4 in dimethyl ketone. Above the tank were squeeze rollers and excess resin was removed from the tape as it passed through. A vertical tower with circulating hot air was used to dry the tape before rewind upon cores with an interleaved strip of silicone treated paper separating each layer.

90 The wound cores were then placed in polyethylene bags in which the air had been displaced by dry nitrogen before sealing. The bags were then placed in sealed opaque containers and half were stored under refrigeration at 35°F and the others at 70°F. At intervals of a few weeks a container was opened and a strip of the unrolled tape exposed to ultraviolet radiation as a test for package stability of the system. It was found that room temperature storage gave good results for periods in excess of three months, and in refrigerated storage for periods of at least nine months.

Example 11

105 Several bias weave cotton bandages were impregnated with the resin system of Example 5 in a similar manner to the techniques of Example 10.

110 An orthopedic test subject was chosen, and the forearm prepared by placing a stockinette sheath around the arm. Over this was placed and taped in place a cushion of ½" thick soft flexible urethane foam. A wrapping of 0.002" polyethylene sheet was then provided over the foam. The pre-impregnated cotton bandages were then wrapped over the covered areas of the arm to form a sheath with an average thickness of 0.100". A medical type ultraviolet lamp was then used to irradiate the bandage surfaces from a distance of 12". Within 30 minutes the surface was hard, rigid and very light in weight. No discomfort was reported by the test subject either from heat or fumes. A radiograph taken through the case showed no impediment to X-rays due to the cast, and showed that X-ray examination was practical with the cast in place.

125 The technique of this invention provides an orthopedic device to which may be attached; for example, bolts, clamps, or any 130

other anchor or holding attachment, threaded or unthreaded. These attachments may be used for pulling, lifting or suspending, as in traction or for therapy purposes. The devices of our invention are applicable not only to members of the human body, but also to animal members.

The casts can be removed by any of the conventional means used for removal of plaster casts, i.e., by using a vibratory saw.

WHAT WE CLAIM IS:—

1. A method for the formation of an orthopedic device which comprises enclosing a body member, as hereinbefore defined, in a fabric impregnated with an ultraviolet radiation-curable organic material, which fabric is substantially free of excess liquid, and curing said material by exposure to ultraviolet irradiation to form a hard device.

2. A method as claimed in claim 1, wherein a fabric in the form of a bandage strip is wrapped around said body member.

3. A method as claimed in claim 1 or claim 2, wherein the device is an orthopedic cast.

4. A method as claimed in any one of claims 1 to 3, wherein the member is covered with a stockinette and/or a plastics wrap before the application of the impregnated fabric.

5. A method as claimed in claim 4, wherein the sockinette and/or the plastics wrap is removed after curing.

6. A method as claimed in any one of claims 1 to 5, wherein the curing is effected at room temperature.

7. A method as claimed in any one of claims 1 to 6, wherein the material is cured by exposure to sunlight.

8. A method as claimed in any one of claims 1 to 7, wherein the material is cured using an ultraviolet lamp.

9. A method as claimed in any one of claims 1 to 8, wherein the fabric is made of cotton.

10. A method as claimed in any one of claims 1 to 8, wherein the fabric is a fibre-class fabric.

11. A method as claimed in any one of claims 1 to 10, wherein the ultraviolet radiation-curable organic material comprises an unsaturated polyester.

12. A method as claimed in claim 11, wherein the ultraviolet radiation-curable organic material is a resin comprising an unsaturated polyester, a terminally ethylenically unsaturated monomer and a photoinitiator.

13. A method as claimed in claim 12, wherein the resin comprises an unsaturated polyester, from 5 to 50% by weight based on the weight of the resin of a terminally ethylenically unsaturated monomer and from 0.002% to 5% by weight, based on the weight of the resin, of a photoinitiator.

14. A method as claimed in claims 12 or 13, wherein the terminally ethylenically unsaturated monomer is styrene.

15. A method as claimed in claims 12 or 13, wherein the terminally ethylenically unsaturated monomer is methyl methacrylate.

16. A method as claimed in claims 12 or 13, wherein the terminally ethylenically unsaturated monomer contains an allyl radical.

17. A method as claimed in claim 16, wherein the terminally ethylenically unsaturated monomer is triallyl cyanurate.

18. A method as claimed in any one of claims 12 to 17, wherein the photoinitiator is benzoin.

19. A method as claimed in any one of claims 12 to 17, wherein the photoinitiator is a hydroxybenzophenone.

20. A method as claimed in any one of claims 12 to 17, wherein the photoinitiator is an azonitrile.

21. A method as claimed in any one of claims 1 to 12, wherein the ultraviolet radiation-curable material is a resin comprising a polymethacrylate dissolved in a monomeric methacrylate and containing a photoinitiator.

22. A method as claimed in any one of claims 1 to 14, wherein the ultraviolet radiation-curable material is a resin comprising an unsaturated polyester, about 30% by weight styrene and about 1% by weight benzoin.

23. A method as claimed in claim 1, carried out substantially as described in Example 11 herein.

24. A length of bandage material which is impregnated with an ultraviolet radiation-curable organic material and is suitable for use in a method as claimed in any one of claims 2 to 23.

25. An orthopedic device whenever prepared by a method as claimed in any one of claims 1 to 23.

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SPECIFICATION NO. 1,245,937

By a direction given under Section 17 (1) of the Patents Act 1949 this application proceeded in the name of MERCK & CO., INC., a Corporation organised under the laws of the State of New Jersey of Rahway, New Jersey, United States of America.

THE PATENT OFFICE

R 5261/7



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other anchor or holding attachment, threaded or unthreaded. These attachments may be used for pulling, lifting or suspending, as in traction or for therapy purposes. The devices of our invention are applicable not only to members of the human body, but also to animal members.

The casts can be removed by any of the conventional means used for removal of plaster casts, i.e., by using a vibratory saw.

WHAT WE CLAIM IS:—

1. A method for the formation of an orthopedic device which comprises enclosing a body member, as hereinbefore defined, in a fabric impregnated with an ultraviolet radiation-curable organic material, which fabric is substantially free of excess liquid, and curing said material by exposure to ultraviolet irradiation to form a hard device.

2. A method as claimed in claim 1, wherein a fabric in the form of a bandage strip is wrapped around said body member.

3. A method as claimed in claim 1 or claim 2, wherein the device is an orthopedic cast.

4. A method as claimed in any one of claims 1 to 3, wherein the member is covered with a stockinette and/or a plastics wrap before the application of the impregnated fabric.

5. A method as claimed in claim 4, wherein the sockinette and/or the plastics wrap is removed after curing.

6. A method as claimed in any one of claims 1 to 5, wherein the curing is effected at room temperature.

7. A method as claimed in any one of claims 1 to 6, wherein the material is cured by exposure to sunlight.

8. A method as claimed in any one of claims 1 to 7, wherein the material is cured using an ultraviolet lamp.

9. A method as claimed in any one of claims 1 to 8, wherein the fabric is made of cotton.

10. A method as claimed in any one of claims 1 to 8, wherein the fabric is a fibre-class fabric.

11. A method as claimed in any one of claims 1 to 10, wherein the ultraviolet radiation-curable organic material comprises an unsaturated polyester.

12. A method as claimed in claim 11, wherein the ultraviolet radiation-curable organic material is a resin comprising an unsaturated polyester, a terminally ethylenically unsaturated monomer and a photoinitiator.

13. A method as claimed in claim 12, wherein the resin comprises an unsaturated polyester, from 5 to 50% by weight based on the weight of the resin of a terminally ethylenically unsaturated monomer and from 0.002% to 5% by weight, based on the weight of the resin, of a photoinitiator.

14. A method as claimed in claims 12 or 13, wherein the terminally ethylenically unsaturated monomer is styrene.

15. A method as claimed in claims 12 or 13, wherein the terminally ethylenically unsaturated monomer is methyl methacrylate.

16. A method as claimed in claims 12 or 13, wherein the terminally ethylenically unsaturated monomer contains an allyl radical.

17. A method as claimed in claim 16, wherein the terminally ethylenically unsaturated monomer is triallyl cyanurate.

18. A method as claimed in any one of claims 12 to 17, wherein the photoinitiator is benzoin.

19. A method as claimed in any one of claims 12 to 17, wherein the photoinitiator is a hydroxybenzophenone.

20. A method as claimed in any one of claims 12 to 17, wherein the photoinitiator is an azonitrile.

21. A method as claimed in any one of claims 1 to 12, wherein the ultraviolet radiation-curable material is a resin comprising a polymethacrylate dissolved in a monomeric methacrylate and containing a photoinitiator.

22. A method as claimed in any one of claims 1 to 14, wherein the ultraviolet radiation-curable material is a resin comprising an unsaturated polyester, about 30% by weight styrene and about 1% by weight benzoin.

23. A method as claimed in claim 1, carried out substantially as described in Example 11 herein.

24. A length of bandage material which is impregnated with an ultraviolet radiation-curable organic material and is suitable for use in a method as claimed in any one of claims 2 to 23.

25. An orthopedic device whenever prepared by a method as claimed in any one of claims 1 to 23.

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SPECIFICATION NO. 1,245,937

By a direction given under Section 17 (1) of the Patents Act 1949 this application proceeded in the name of MERCK & CO., INC., a Corporation organised under the laws of the State of New Jersey of Rahway, New Jersey, United States of America.