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(54) METHOD OF FORMING AN OCULAR MEMBRANE

(71) I, William Seth Covington, a citizen of the United States of America, of Litchfield County, West Cornwall, Connecticut 06796, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement: —

This invention relates to a method of forming an ocular membrane.

The present invention provides a method of forming an ocular membrane from a polymerizable material suitable for use as a contact lens, comprising the steps of:

— forming ophthalmically contoured concave and convex mould members;
— introducing the polymerizable material into the concave mould member;
— contacting the convex mould member with the concave mould member to form a substantially closed mould chamber;
— subjecting the thus-introduced polymerizable material to polymerization conditions to form a polymeric ocular membrane from the said material possessing the contours of the substantially closed mould chamber; and
— freeing the formed ocular membrane from the substantially closed mould chamber.

The polymerizable material utilized in the method according to the invention may be a composition as described and claimed in my copending application no. 48502/78 (Serial No. 1,584,882), i.e. it is a composition which includes or consists of a copolymer of a polysiloxane and a compound selected from (a) esters of glycidyl alcohol with acrylic acid or methacrylic acid and (b) maleic anhydride, the maleic anhydride adduct of methylcyclopentadiene, or hexahydrophthalic anhydride, the amount of such compound in the composition being effective to impart wettability to the surface of articles formed from the composition (i.e. the surface of ocular membranes or contact lenses formed from the composition wet sufficiently so as to maintain uninterrupted refractive functioning) but less than that which would destroy the hydrophobic properties of the composition (i.e. the composition is non-water swellable).

The method according to the invention for producing ultrathin ocular membranes is easily adaptable to mass production methods, and may substantially reduce the cost of such membranes in relation to presently available contact lenses.

Attention is also drawn to my copending application no. 48503/78 (Serial No. 1,584,883).

The invention will be further described by way of example only, with reference to the accompanying drawings, in which:

Figure 1 shows a cured ocular membrane in relation to the mold surfaces used in its formation;

Figure 2 is an enlarged view of a portion of the mold shown in Figure 1; and

Figures 3 to 6 depict sequential steps in the method of the present invention.

An ocular membrane is prepared by the method of the present invention by first forming a lens mold cavity composed of two mold members, a concave member and a convex member. The convex member is a replica of the ocular surface with a small pupillary segment conforming in its geometry to the topography of the human cornea. Of course, the pupillary segment in the concave member of the mold would conform to the specifications of the opthalmic prescription.

The mold members are made from plastics materials which are soluble in solvents in which the lens copolymer is not soluble. Examples of suitable materials which can be used as the mold members include, but are not limited to, polymethylmethacrylate, ethyl cellulose, cellulose acetate, polystyrene, vinyl acetate, epoxy, methyl cellulose acetate, acrylonitrile butadiene styrene copolymer and carnauba wax.

A die for forming the mold members is first made. It can be made from a calcium sulphate impression which, utilizing conventional methods, is formed by making an impression of the human eye or, alternatively, an impression of a life-size model of the human eye. The die is generally made of a metal, e.g. steel, chrome, or nickel.

An impression may be made of the entire sclera and cornea; a part of the sclera and all of the cornea; or alternatively, only of the cornea itself, in whole or in part. Whichever impression is made, it is, of course, ultimately transferred to the final ocular membrane. Thus, depending upon the particular prescription, the ocular membrane made according to the method of the present invention will cover either the entire sclera and all of the cornea, or only part of the sclera and all of the cornea, or only cover the cornea, in whole or in part. The convex mold possesses a configuration identical to the concave mold with the exception of a central pupillary area which possesses geometry and dimensions as dictated by the specific refractive ophthalmic prescription being used. In addition, the concave mold is so shaped so as to permit it and the convex mold to meet uniformly over the entire perimeter of the two molds when brought together.

The thermoplastics molds are made by conventional casting, injection-molding, or compression molding methods utilizing metallic master dies, as previously mentioned. They may be formed from calcium sulphate impressions of the eye or, alternatively, machined to duplicate standardized models of the human eye topography over the entire range thereof. This procedure permits perfect duplication of either unique models or standard models of ocular topography through the use of various plastics materials.

The relationship of the molds and membrane is shown in Figure 1, and the method by which the molds are used to form the membrane is shown in Figures 3 to 6.

In Figure 1, the mold assembly generally indicated at 52 has a convex mold 54 positioned above a concave mold 56. The concave mold 56 has a central pupillary portion 64 and has a raised circumferential annular surface 57 of radius R_3 as shown in Figure 2, which forms an edge on the membrane generally indicated at 59 by intersecting with the radius of curvature R_1 of the convex mold surface 54 because the circumferential annular surface 57 has a steeper radius of curvature than does the radius of curvature of the convex mold surface.

The membrane 59 is shown positioned between the upper convex mold 54 and the lower concave mold 56. The alignment of the upper convex mold 54 with the concave mold 56 is determined by means of the circumferential annular surface 57 or R_3 on the lower mold which coacts with the radius of curvature R_1 on the convex surface of the upper mold. The difference in the radii of curvature between the circumferential annular surface R_3 and the radius of curvature R_1 of the convex mold surface 54 produces the peripheral edge of the membrane 59. The pupillary section of the lens 60 will be accurately positioned with relation to the peripheral edges of the membrane as long as the upper and lower mold sections are in parallel and perpendicular alignment. This is accomplished in a manner well known in the art in which the lower mold member is allowed to slide freely on a horizontal plane so that it will automatically position itself when the upper mold member engages it.

As shown in Figure 3, the first step in the formation of the ocular membrane is to properly position the convex and concave molds 54 and 56 respectively in vertical and horizontal alignment. Then, a copolymer liquid 68 which is a polymerizable material as previously defined is poured from a pouring spout 66 to fill the concave mold to a level sufficient to take up the entire volume that will form the membrane. The upper mold 54 is then lowered onto the lower mold to engage the lower mold and thereby to form a substantially closed mold chamber and, in the process, will expel any excess copolymer liquid which has been deposited in the lower mold.

The mold halves are then left in their engaged position for a period of time sufficient for cross linking to take place. Once this has occurred, because of the relative thinness of the ocular membrane and its intimate contact with the mold surfaces, it would be difficult if not impossible to separate the mold surfaces and remove the ocular membrane without in some way impairing the optical finish of the finished membrane.

Therefore, to avoid this step of removing the membrane from the mold surfaces, the mold may be suitably removed from the membrane by a destruction process in which the material from which the mold is fabricated is placed in contact with another material which is incompatible with the survival of the mold material but which will have no permanent effect on the material forming the ocular membrane. Such a process is shown in Figures 5 and 6, where the mold assembly, generally indicated at 52 is positioned in a vessel 72 filled with, for example, one of the solvents in which the mold material would dissolve but which would not in any way absorb or attack the material from which the ocular membrane is produced. After a sufficient period of time, the mold will be reduced to debris 74 shown in Figure 6 and the membrane 57 will itself float freely in the liquid.

After the membrane has floated free, it can then be removed, washed and dried and further postcuring can be accomplished if desired. Washing is generally done in a sodium chloride solution (three percent is preferred).

It should be noted that the membrane, once released from the mold, is in the finished state and that no further forming process is necessary in order to produce any optical properties of the membrane or any edge, shape or configuration on the lens.

In accordance with one embodiment of the present invention, the removal of the cured ocular membrane from the mold members is accomplished by inserting or submerging the entire assembly into a solvent for the mold members. As noted hereinabove, this solvent should be a non-solvent for the cured contact lens or ocular membrane composition but should be a good solvent for the mold material.

The following table sets forth a number of suitable plastics materials which can be used to make the mold and solvents which can be used in conjunction with them.

Mold Material	*Solvent*
polymethyl methacrylate	acetone
ethyl cellulose	ethyl alcohol
cellulose acetate	methyl ethyl ketone
polystyrene	toluene
vinyl acetate	methyl alcohol
epoxy	isophorone
methyl cellulose acetate	water
acrylonitrile butadiene styrene	methyl ethyl ketone
carnauba wax	benzene.

WHAT I CLAIM IS:—

1. A method of forming an ocular membrane from a polymerizable material suitable for use as a contact lens, comprising the steps of:
— forming ophthalmically contoured concave and convex mould members;
— introducing the polymerizable material into the concave mould member;
— contacting the convex mould member with the concave mould member to form a substantially closed mould chamber;
— subjecting the thus-introduced polymerizable material to polymerization conditions to form a polymeric ocular membrane from the said material possessing the contours of the substantially closed mould chamber; and
— freeing the formed ocular membrane from the substantially closed mould chamber, wherein the polymerizable material is a composition which includes or consists of a copolymer of a polysiloxane and a compound selected from (a) esters of glycidyl alcohol with acrylic or methacrylic acid and (b) maleic anyhdride, the maleic anhydride adduct of methyl cyclopentadiene, or hexahydrophthalic anhydride, the amount of such compound in the said composition being effective to impart wettability (as hereindefined) to the surface of articles formed from the composition but less than that which would destroy the hydrophobic properties (as hereindefined) of the composition.

2. A method according to Claim 1 of forming an ocular membrane, substantially as herein described with reference to figures 1 to 4 of the accompanying drawings.

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1584884 COMPLETE SPECIFICATION

1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

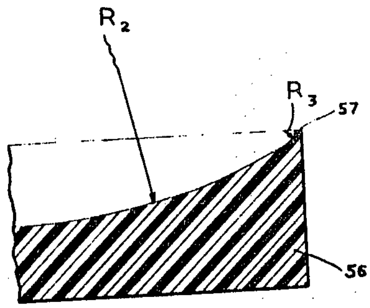

FIG. 2

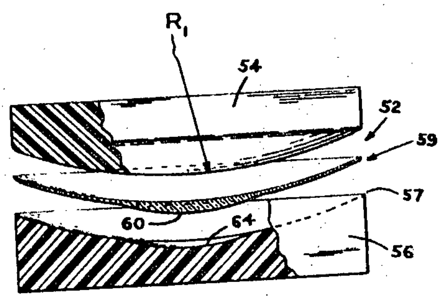

FIG. 1

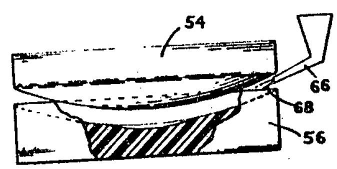

FIG. 3

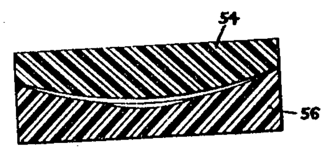

FIG. 4

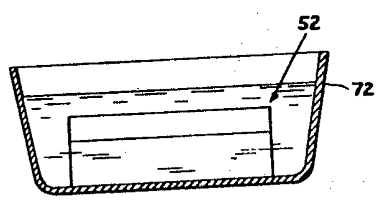

FIG. 5

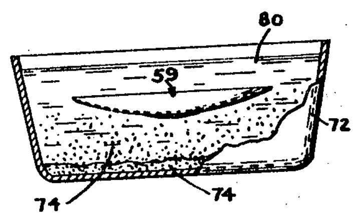

FIG. 6