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(54) Title: METHOD FOR MAKING EMBEDDED HYDROGEL CONTACT LENSES

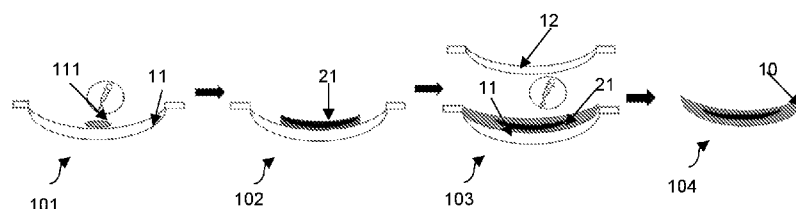


Figure 1

(57) Abstract: A method for producing embedded hydrogel contact lenses comprises at least the following steps: depositing a small drop of a viscous lens-forming composition in the center of a female lens mold half; placing a preformed insert on top of the small drop precisely in the center of the female lens mold half so that the insert is held by capillary forces due to the presence of a thin layer of the viscous lens-forming composition between the insert and the molding surface of the female lens mold half; dosing an amount of another less viscous lens-forming composition on top of the insert to immerse the insert in the female lens mold half; closing tightly a male lens mold half onto the top of the female lens mold half halves to form a molding assembly; curing both the lens-forming compositions in the molding assembly to form an embedded hydrogel lens precursor.



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Method for Making Embedded Hydrogel Contact Lenses

The present invention generally relates to a method for producing embedded hydrogel contact lenses. In addition, the present invention provides embedded hydrogel contact lenses produced according to a method of the invention.

BACKGROUND

Hydrogel contact lenses are widely used for correcting many different types of vision deficiencies due to their softness for wearing comfort. They are made of a hydrated, crosslinked polymeric material that contains from about 20% to about 75% by weight of water within the lens polymer matrix at equilibrium. Hydrogel contact lenses generally are produced according to the conventional full cast-molding process. Such a conventional manufacturing process comprises at least the following steps: lens molding (i.e., curing a polymerizable composition in lens molds), demolding (i.e., removing lenses from molds), extracting lenses with an extraction medium, hydrating lenses, packaging and sterilizing the hydrated lenses. During the lens hydration, the hydrogel contact lenses will absorb water and typically can swell significantly in size.

In recent years, it has been proposed that various inserts can be incorporated in hydrogel contact lenses for various purposes, e.g., for corneal health, vision correction, diagnosis, etc. See, for example, U.S. Pat. Nos. 4268132, 4401371, 5098546, 5156726, 6851805, 7104648, 7490936, 7883207, 7931832, 8154804, 8215770, 8348424, 8874182, 8922898, 9155614, 9176332, 9296158, 9618773, 9731437, 9889615, 9977260, 10203521, and 10209534; and U.S. Pat. Appl. Pub. Nos. 2004/0141150, 2009/0091818, 2010/0076553, 2011/0157544, and 2012/0140167).

An insert typically needs to be placed and fixed precisely in a specifically designed position in an embedded hydrogel contact lens. It is a great challenge to produce embedded hydrogel contact lenses that comprise one or more inserts embedded in specific positions in the embedded hydrogel contact lenses. A typical approach is to use molds having positioning guides (posts) provided on their molding surface for cast-molding embedded hydrogel contact lenses. Those positioning guides (posts) provides means for precisely positioning inserts in molds during cast-molding process. However, by using such molds with positioning guides (posts), small holes derived from those positioning guides (posts) are formed in resultant embedded hydrogel contact lenses. Those small holes in the embedded hydrogel lenses are susceptible to bioburden trapping.

U.S. Pat. No. 9581832 discloses one approach for eliminating positioning guides (posts) in a method for making embedded hydrogel contact lenses. A method of US9581832 comprises the steps of: depositing an initial amount of a reactive monomer mixture into a

front curve mold part; placing a rigid insert on the initial amount of the reactive monomer mixture; precuring the initial amount of the reactive monomer mixture to fixedly hold the rigid insert proximate to the front curve mold part to form a front curve assembly; depositing an additional amount of the reactive monomer mixture necessary for formation of the contact lens into the front curve assembly; placing a back curve mold part proximate to the front curve assembly; curing the initial and additional amounts of reactive monomer mixture to form the embedded contact lens. However, there are issues associated with this approach. For example, the precuring step in combination with the curing step can lead to a cured material that can have potentially mechanical properties different from the rest lens bulk material and consequently can alter the shape of the final lens, as evidenced by the formation ridges and rings around the insert. Furthermore, hazy rings can be formed in the insert zone if curing intensities and times are too long.

Therefore, there is still a need for producing embedded hydrogel contact lenses (preferably embedded silicone hydrogel contact lenses) having inserts positioned accurately therein in a relatively efficient and consistent manner and which can be readily implemented in a production environment.

SUMMARY OF THE INVENTION

In one aspect, the invention provides a method for producing embedded hydrogel contact lenses, the method of invention comprising the steps of: (1) obtaining a first lens-forming composition and a second lens-forming composition, wherein the first and second lens-forming compositions comprise identical polymerizable components (materials) but different non-reactive diluents, wherein the first lens-forming composition comprises a first non-reactive diluent and the second lens-forming composition comprises a second non-reactive diluent, wherein difference (ΔC_i) in the concentration of each polymerizable components (materials) between in the first lens-forming composition and in the second lens-forming composition is less than 10.0%, wherein $\Delta C_i = \frac{|C_{2i} - C_{1i}|}{C_{2i}} \times 100\%$ in which C_{1i} and C_{2i} are the concentrations of polymerizable component i in the first and second lens-forming compositions respectively, wherein ratio of the viscosity of the first lens-forming composition over the viscosity of the second lens-forming composition is at least 1.5; (2) obtaining a lens mold, wherein the lens mold comprises a female lens mold half and a male lens mold half, wherein the female lens mold half has a first molding surface and a first central axis, wherein the male lens mold half has a second molding surface and a second central axis, wherein the first molding surface defines the anterior surface of an embedded hydrogel contact lens, wherein the second molding surface defines the posterior surface of the embedded hydrogel contact lens, wherein the female and male lens mold halves are configured to receive each

other such that a mold cavity is formed between the first and second molding surfaces when the mold is closed; (3) obtaining an insert which is made of a polymeric material and comprises a front surface, an opposite back surface, a third central axis, and a diameter up to about 13.0 mm; (4) dosing from about 1 to about 20 μL of the first lens-forming composition in the center of the first molding surface of the female lens mold half; (5) placing the insert on top of the first lens-forming composition on the first molding surface of the female lens mold half in a way to ensure that the third central axis coincides with the first central axis and the insert is held at a position above the first molding surface of the female lens mold half; (6) placing the male lens mold half on top of the female lens mold half and closing the male and female lens mold halves to form a molding assembly comprising the first and second lens-forming compositions and the insert immersed therein in the molding assembly; (7) curing the first and second lens-forming compositions in the molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the first and second lens-forming compositions and the insert embedded in the bulk hydrogel material and centered in the embedded hydrogel lens precursor; (8) separating the lens mold obtained in step (7) into the male and female lens mold halves, with the embedded hydrogel lens precursor adhered on a lens-adhered lens mold half which is one of the male and female lens mold halves; (9) removing the embedded hydrogel lens precursor from the lens-adhered lens mold half (preferably before the embedded hydrogel lens precursor is contact with water or any liquid); and (10) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

In another aspect, the invention provides an embedded hydrogel contact lens obtained according to a method of the invention.

These and other aspects of the invention will become apparent from the following description of the presently preferred embodiments. The detailed description is merely illustrative of the invention and does not limit the scope of the invention, which is defined by the appended claims and equivalents thereof. As would be obvious to one skilled in the art, many variations and modifications of the invention may be effected without departing from the spirit and scope of the novel concepts of the disclosure.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 schematically illustrates the flow chart of a process for making embedded hydrogel contact lenses according to a preferred embodiment of the invention.

Figure 2 shows the image of a cross section of an embedded silicone hydrogel

contact lens produced according to a preferred embodiment of the invention.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Generally, the nomenclature used herein and the laboratory procedures are well known and commonly employed in the art. Conventional methods are used for these procedures, such as those provided in the art and various general references. Where a term is provided in the singular, the inventors also contemplate the plural of that term. The nomenclature used herein and the laboratory procedures described below are those well-known and commonly employed in the art.

"About" as used herein in this application means that a number, which is referred to as "about", comprises the recited number plus or minus 1-10% of that recited number.

"Contact Lens" refers to a structure that can be placed on or within a wearer's eye. A contact lens can correct, improve, or alter a user's eyesight, but that need not be the case. A contact lens can be of any appropriate material known in the art or later developed, and can be a soft lens, a hard lens, or an embedded lens.

A "hydrogel contact lens" refers to a contact lens comprising a hydrogel bulk (core) material. A hydrogel bulk material can be a non-silicone hydrogel material or preferably a silicone hydrogel material.

A "hydrogel" or "hydrogel material" refers to a crosslinked polymeric material which has three-dimensional polymer networks (i.e., polymer matrix), is insoluble in water, but can hold at least 10% by weight of water in its polymer matrix when it is fully hydrated (or equilibrated).

A siloxane, which often also described as a silicone, refers to a molecule having at least one moiety of -Si-O-Si- where each Si atom carries two organic groups as substituents.

A "silicone hydrogel" or "SiHy" refers to a silicone-containing hydrogel obtained by copolymerization of a polymerizable composition comprising at least one silicone-containing monomer or at least one silicone-containing macromer or at least one crosslinkable silicone-containing prepolymer.

As used in this application, the term "non-silicone hydrogel" or "non-silicone hydrogel material" interchangeably refers to a hydrogel that is theoretically free of silicon.

A "male mold half" or "base curve mold half" interchangeably refers to a mold half having (1) a molding surface that is a substantially convex surface and that defines the posterior (back) surface of a contact lens (or an insert) and (2) a central axis that is the normal line at the center of the molding surface.

A “female mold half” or “front curve mold half” interchangeably refers to a mold half having (1) a molding surface that is a substantially concave surface and that defines the anterior (front) surface of a contact lens (or an insert) and (2) a central axis that is the normal line at the center of the molding surface.

The term “anterior surface”, “front surface”, “front curve surface” or “FC surface” in reference to a contact lens or an insert, as used in this application, interchangeably means a surface of the contact lens or insert that faces away from the eye during wear. The anterior surface (front surface) is typically substantially convex.

The “posterior surface”, “back surface”, “base curve surface” or “BC surface” in reference to a contact lens or insert, as used in this application, interchangeably means a surface of the contact lens or insert that faces towards the eye during wear. The posterior surface (back surface) is typically substantially concave.

An “embedded hydrogel contact lens” refers a hydrogel contact lens comprising at least one insert which is embedded fully or partially within the bulk hydrogel material of the embedded hydrogel contact lens.

In this application, an “insert” refers to any preformed article which has a diameter of up to 13 mm, a front (anterior) surface, an opposite back (posterior) surface, a central axis, and a thickness less than any thickness of an embedded hydrogel contact lens in the region where the insert is embedded. It is understood that the insert must be smaller than the embedded hydrogel contact lens in dimension, so as to be embedded in the bulk material of the embedded hydrogel contact lens. The insert can be made of a polymeric material that can be a non-hydrogel material or a hydrogel material. Examples of preferred inserts include without limitation thin rigid inserts for providing rigid center optics for masking astigmatism like a rigid gas permeable (RGP) contact lens, multifocal lens inserts, photochromic inserts, cosmetic inserts having color patterns printed thereon, etc.

In this application, a central axis of an insert (or contact lens) refers to an imaginary line passing through both the centers of the anterior (front) and posterior (back) surface of the insert (or contact lens).

In accordance with the invention, a non-hydrogel material can be any material that can absorb less than 5% (preferably about 4% or less, more preferably about 3% or less, even more preferably about 2% or less) by weight of water when being fully hydrated.

“Hydrophilic,” as used herein, describes a material or portion thereof that will more readily associate with water than with lipids.

“Hydrophobic” in reference to an insert material or insert that has an equilibrium water content (i.e., water content in fully hydrated state) of less than 5% (preferably about 4% or less, more preferably about 3% or less, even more preferably about 2% or less).

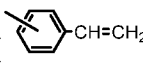
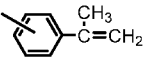
The term “room temperature” refers to a temperature of about 22°C to about 26°C.

The term “soluble”, in reference to a compound or material in a solvent, means that the compound or material can be dissolved in the solvent to give a solution with a concentration of at least about 0.5% by weight at room temperature (i.e., a temperature of about 22°C to about 26°C).

The term “insoluble”, in reference to a compound or material in a solvent, means that the compound or material can be dissolved in the solvent to give a solution with a concentration of less than 0.01% by weight at room temperature (as defined above).

A “vinyl monomer” refers to a compound that has one sole ethylenically unsaturated group, is soluble in a solvent, and can be polymerized actinically or thermally.

As used in this application, the term “ethylenically unsaturated group” is employed herein in a broad sense and is intended to encompass any groups containing at least one $>C=CH_2$ group. Exemplary ethylenically unsaturated groups include without limitation

(meth)acryloyl ($-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-\overset{\text{CH}_3}{\text{C}}=CH_2$ and/or $-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-CH=CH_2$), vinyloxycarbonylamino ($-\text{NR}^0-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-O-CH=CH_2$ in which R^0 is H or C_1 - C_4 alkyl), vinyloxycarbonyloxy ($-O-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-O-CH=CH_2$), vinylaminocarbonylamino ($-\text{NR}^0-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-NH-CH=CH_2$ in which R^0 is H or C_1 - C_4 alkyl), vinylaminocarbonyloxy ($-O-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-NH-CH=CH_2$), allyl, vinyl, styrenyl ( or , or other $C=C$ containing groups.

An “acrylic monomer” refers to a vinyl monomer having one sole (meth)acryloyl group. Examples of acrylic monomers includes (meth)acryloxy [or(meth)acryloyloxy] monomers and (meth)acrylamido monomers.

An “(meth)acryloxy monomer” or “(meth)acryloyloxy monomer” refers to a vinyl monomer having one sole group of $-\text{O}-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-\overset{\text{CH}_3}{\text{C}}=CH_2$ or $-\text{O}-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-CH=CH_2$.

An “(meth)acrylamido monomer” refers to a vinyl monomer having one sole group of $-\text{NR}^0-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-\overset{\text{CH}_3}{\text{C}}=CH_2$ or $-\text{NR}^0-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-CH=CH_2$ in which R^0 is H or C_1 - C_4 alkyl.

The term “aryl acrylic monomer” refers to an acrylic monomer having at least one aromatic ring.

An “(meth)acryloxy monomer” or “(meth)acryloyloxy monomer” refers to a vinyl monomer having one sole group of $-\text{O}-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-\overset{\text{CH}_3}{\text{C}}=CH_2$ or $-\text{O}-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-CH=CH_2$.

An “(meth)acrylamido monomer” refers to a vinyl monomer having one sole group of $-\text{NR}^0-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-\overset{\text{CH}_3}{\text{C}}=CH_2$ or $-\text{NR}^0-\overset{\text{O}}{\underset{\text{O}}{\text{C}}}-CH=CH_2$ in which R^0 is H or C_1 - C_4 alkyl.

The term “(meth)acrylamide” refers to methacrylamide and/or acrylamide.

The term “(meth)acrylate” refers to methacrylate and/or acrylate.

An “N-vinyl amide monomer” refers to an amide compound having a vinyl group ($-\text{CH}=\text{CH}_2$) that is directly attached to the nitrogen atom of the amide group.

An “ene monomer” refers to a vinylic monomer having one sole ene group.

A “hydrophilic vinylic monomer”, a “hydrophilic acrylic monomer”, a “hydrophilic (meth)acryloxy monomer”, or a “hydrophilic (meth)acrylamido monomer”, as used herein, respectively refers to a vinylic monomer, an acrylic monomer, a (meth)acryloxy monomer, or a (meth)acrylamido monomer, which typically yields a homopolymer that is water-soluble or can absorb at least 10 percent by weight of water.

A “hydrophobic vinylic monomer”, a “hydrophobic acrylic monomer”, a “hydrophobic (meth)acryloxy monomer”, or a “hydrophobic (meth)acrylamido monomer”, as used herein, respectively refers to a vinylic monomer, an acrylic monomer, a (meth)acryloxy monomer, or a (meth)acrylamido monomer, which typically yields a homopolymer that is insoluble in water and can absorb less than 10% by weight of water.

As used in this application, the term “vinylic crosslinker” refers to an organic compound having at least two ethylenically unsaturated groups. A “vinylic crosslinking agent” refers to a vinylic crosslinker having a molecular weight of 700 Daltons or less.

An “acrylic crosslinker” refers to a vinylic crosslinker having at least two (meth)acryloyl groups.

The term “acrylic repeating units” refers to repeating units of a polymeric material, each of which is derived from an acrylic monomer or crosslinker in a free-radical polymerization to form the polymeric material.

The term “terminal (meth)acryloyl group” refers to one (meth)acryloyl group at one of the two ends of the main chain (or backbone) of an organic compound as known to a person skilled in the art.

As used herein, “actinically” in reference to curing, crosslinking or polymerizing of a polymerizable composition, a prepolymer or a material means that the curing (e.g., crosslinked and/or polymerized) is performed by actinic irradiation, such as, for example, UV/visible irradiation, ionizing radiation (e.g. gamma ray or X-ray irradiation), microwave irradiation, and the like. Thermal curing or actinic curing methods are well-known to a person skilled in the art.

As used in this application, the term “polymer” means a material formed by polymerizing/crosslinking one or more monomers or macromers or prepolymers or combinations thereof.

A “macromer” or “prepolymer” refers to a compound or polymer that contains ethylenically unsaturated groups and has a number average molecular weight of greater than 700 Daltons.

As used in this application, the term “molecular weight” of a polymeric material (including monomeric or macromeric materials) refers to the number-average molecular weight unless otherwise specifically noted or unless testing conditions indicate otherwise. A skilled person knows how to determine the molecular weight of a polymer according to known methods, e.g., GPC (gel permeation chromatography) with one or more of a refractive index detector, a low-angle laser light scattering detector, a multi-angle laser light scattering detector, a differential viscometry detector, a UV detector, and an infrared (IR) detector; MALDI-TOF MS (matrix-assisted desorption/ionization time-of-flight mass spectroscopy); ¹H NMR (Proton nuclear magnetic resonance) spectroscopy, etc.

A “polysiloxane segment” or “polydiorganosiloxane segment” interchangeably refers

to a polymer chain segment (i.e., a divalent radical) of
$$\left[\begin{array}{c} \text{R}_{\text{S1}} \\ | \\ \text{---Si---O---} \\ | \\ \text{R}_{\text{S2}} \end{array} \right]_{\text{SN}} \begin{array}{c} \text{R}_{\text{S1}} \\ | \\ \text{---Si---} \\ | \\ \text{R}_{\text{S2}} \end{array}$$
 in which SN is an integer of 3 or larger and each of R_{S1} and R_{S2} independent of one another are selected from the group consisting of: C₁-C₁₀ alkyl; phenyl; C₁-C₄-alkyl-substituted phenyl; C₁-C₄-alkoxy-substituted phenyl; phenyl-C₁-C₆-alkyl; C₁-C₁₀ fluoroalkyl; C₁-C₁₀ fluoroether; aryl; aryl C₁-C₁₈ alkyl; -alk-(OC₂H₄)_{γ1}-OR^o (in which alk is C₁-C₆ alkylene diradical, R^o is H or C₁-C₄ alkyl and γ1 is an integer from 1 to 10); a C₂-C₄₀ organic radical having at least one functional group selected from the group consisting of hydroxyl group (-OH), carboxyl group (-COOH), amino group (-NR_{N1}R_{N1'}), amino linkages of -NR_{N1}-, amide linkages of -CONR_{N1}-, amide of -CONR_{N1}R_{N1'}, urethane linkages of -OCONH-, and C₁-C₄ alkoxy group, or a linear hydrophilic polymer chain, in which R_{N1} and R_{N1'} independent of each other are hydrogen or a C₁-C₁₅ alkyl; and a photochromic organic radical having a photochromic group.

A “polysiloxane vinylic monomer” refers to a compound comprising at least one polysiloxane segment and one sole ethylenically-unsaturated group.

A “polydiorganosiloxane vinylic crosslinker” or polysiloxane vinylic crosslinker” interchangeably refers to a compound comprising at least one polysiloxane segment and at least two ethylenically-unsaturated groups.

A “linear polydiorganosiloxane vinylic crosslinker” or “linear polysiloxane vinylic crosslinker” interchangeably refers to a compound comprising a main chain which includes at least one polysiloxane segment and is terminated with one ethylenically-unsaturated group at each of the two ends of the main chain.

A “chain-extended polydiorganosiloxane vinylic crosslinker” or “chain-extended polysiloxane vinylic crosslinker” interchangeably refers to a compound comprising at least two ethylenically-unsaturated groups and at least two polysiloxane segments each pair of which are linked by one divalent radical.

The term “fluid” as used herein indicates that a material is capable of flowing like a

liquid.

As used in this application, the term “clear” in reference to a polymerizable composition means that the polymerizable composition is a transparent solution or liquid mixture (i.e., having a light transmissibility of 85% or greater, preferably 90% or greater in the range between 400 to 700 nm).

The term “monovalent radical” refers to an organic radical that is obtained by removing a hydrogen atom from an organic compound and that forms one bond with one other group in an organic compound. Examples include without limitation, alkyl (by removal of a hydrogen atom from an alkane), alkoxy (or alkoxyl) (by removal of one hydrogen atom from the hydroxyl group of an alkyl alcohol), thiyl (by removal of one hydrogen atom from the thiol group of an alkylthiol), cycloalkyl (by removal of a hydrogen atom from a cycloalkane), cycloheteroalkyl (by removal of a hydrogen atom from a cycloheteroalkane), aryl (by removal of a hydrogen atom from an aromatic ring of the aromatic hydrocarbon), heteroaryl (by removal of a hydrogen atom from any ring atom), amino (by removal of one hydrogen atom from an amine), etc.

The term “divalent radical” refers to an organic radical that is obtained by removing two hydrogen atoms from an organic compound and that forms two bonds with other two groups in an organic compound. For example, an alkylene divalent radical (i.e., alkylenyl) is obtained by removal of two hydrogen atoms from an alkane, a cycloalkylene divalent radical (i.e., cycloalkylenyl) is obtained by removal of two hydrogen atoms from the cyclic ring.

In this application, the term “substituted” in reference to an alkyl or an alkylenyl means that the alkyl or the alkylenyl comprises at least one substituent which replaces one hydrogen atom of the alkyl or the alkylenyl and is selected from the group consisting of hydroxyl (-OH), carboxyl (-COOH), -NH₂, sulfhydryl (-SH), C₁-C₄ alkyl, C₁-C₄ alkoxy, C₁-C₄ alkylthio (alkyl sulfide), C₁-C₄ acylamino, C₁-C₄ alkylamino, di-C₁-C₄ alkylamino, and combinations thereof.

A free radical initiator can be either a photoinitiator or a thermal initiator. A “photoinitiator” refers to a chemical that initiates free radical crosslinking/polymerizing reaction by the use of light. A “thermal initiator” refers to a chemical that initiates free radical crosslinking/polymerizing reaction by the use of heat energy.

The “oxygen permeability”, Dk_i , of a material is the rate at which oxygen will pass through a material and can be measured at about 34-35°C according to the procedures described in Example 1. Oxygen permeability is conventionally expressed in units of barrers, where “barrer” is defined as $[(\text{cm}^3 \text{ oxygen})(\text{mm}) / (\text{cm}^2)(\text{sec})(\text{mm Hg})] \times 10^{-10}$.

The “oxygen transmissibility”, Dk/t , of an insert or material is the rate at which oxygen will pass through a specific insert or material with an average thickness of t [in units of mm] over the area being measured. Oxygen transmissibility is conventionally expressed in units

of barrers/mm, where “barrers/mm” is defined as $[(\text{cm}^3 \text{ oxygen})/(\text{cm}^2)(\text{sec})(\text{mm Hg})] \times 10^{-9}$.

The term “modulus” or “elastic modulus” in reference to a contact lens or a material means the tensile modulus or Young’s modulus which is a measure of the stiffness of a contact lens or a material. The modulus can be measured according to the procedures described in Example 1.

In general, the invention is directed to a method for producing embedded hydrogel contact lenses having an insert embedded therein. Figure 1 such a method of the invention. It comprises at least the following steps: a step (101) of depositing a small drop (111) of a viscous lens-forming composition in the center of a female lens mold half (11); a step (102) of placing a preformed insert (21) on top of the small drop (111) precisely in the center of the female lens mold half (11) so that the insert is held by capillary forces due to the presence of a thin layer of the viscous lens-forming composition between the insert and the molding surface of the female lens mold half; steps (103) of dosing an amount of another less viscous lens-forming composition on top of the insert (21) to immerse the insert (21) in the female lens mold half (11), placing a male lens mold half (12) on top of the female lens mold, closing tightly the female and male lens mold halves to form a molding assembly, and curing both the lens-forming compositions in the molding assembly to form an embedded hydrogel lens precursor; a step (104) of removing the embedded hydrogel lens precursor (10) from the molding assembly.

This invention is partly based on the discovery that by using one non-reactive diluent with a high viscosity and another non-reactive diluent with a low viscosity, two lens-forming compositions can be prepared to be substantially identical to each other with respect to all polymerizable components but to differ greatly in viscosity. By having identical compositions with respect to all polymerizable components, resultant hydrogel bulk material can be substantially homogeneous, especially in mechanical properties. This invention is also partly based on the discovery that a viscous lens-forming composition can be used to hold an insert in place by capillary forces during subsequent dosing of a less viscous lens-forming composition, closing mold and curing of lens-forming compositions in the closed mold.

A method of the invention removes the needs for positioning guides (posts) for centrally positioning an insert during molding process. By eliminating positioning guides, any small voids in the lenses from the positioning guides are eliminated, thus removing any potential for bioburden trapping. Further, a precuring step is eliminated in a method of the invention. There is no need for extra precuring equipment. Any mechanical changes associated with the precuring can be avoided and thereby the potential for lens geometry problems can be eliminated. In addition, a method of the invention can be easily implemented in an automatic product line for producing embedded hydrogel contact lenses in mass.

In one aspect, the invention provides a method for producing embedded hydrogel contact lenses, the method of invention comprising the steps of: (1) obtaining a first lens-forming composition and a second lens-forming composition, wherein the first and second lens-forming compositions comprise identical polymerizable components (materials) but different non-reactive diluents, wherein the first lens-forming composition comprises a first non-reactive diluent and the second lens-forming composition comprises a second non-reactive diluent, wherein difference (ΔC_i) in the concentration of each polymerizable components (materials) between in the first lens-forming composition and in the second lens-forming composition is less than 10.0%, wherein $\Delta C_i = \frac{|C_{2i} - C_{1i}|}{C_{2i}} \times 100\%$ in which C_{1i} and C_{2i} are the concentrations of polymerizable component i in the first and second lens-forming compositions respectively, wherein ratio of the viscosity of the first lens-forming composition over the viscosity of the second lens-forming composition is at least 1.5 (preferably at least 2.0, more preferably at least 2.5, even more preferably at least 3.0); (2) obtaining a lens mold, wherein the lens mold comprises a female lens mold half and a male lens mold half, wherein the female lens mold half has a first molding surface and a first central axis, wherein the male lens mold half has a second molding surface and a second central axis, wherein the first molding surface defines the anterior surface of an embedded hydrogel contact lens, wherein the second molding surface defines the posterior surface of the embedded hydrogel contact lens, wherein the female and male lens mold halves are configured to receive each other such that a mold cavity is formed between the first and second molding surfaces when the mold is closed; (3) obtaining an insert which is made of a polymeric material and comprises a front surface, an opposite back surface, a third central axis, and a diameter up to about 13.0 mm; (4) dosing from about 1 to about 20 μL (preferably from about 1 to about 15 μL , more preferably from about 1 to about 10 μL , even more preferably from about 2 to about 6 μL) of the first lens-forming composition in the center of the first molding surface of the female lens mold half; (5) placing the insert on top of the first lens-forming composition on the first molding surface of the female lens mold half in a way to ensure that the third central axis coincides with the first central axis and the insert is held at a position above the first molding surface of the female lens mold half; (6) placing the male lens mold half on top of the female lens mold half and closing the male and female lens mold halves to form a molding assembly comprising the first and second lens-forming compositions and the insert immersed therein in the molding assembly; (7) curing the first and second lens-forming compositions in the molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the first and second lens-forming compositions and the insert embedded in the bulk hydrogel material and centered in the embedded hydrogel lens precursor; (8) separating the lens mold obtained in step (7) into the

male and female lens mold halves, with the embedded hydrogel lens precursor adhered on a lens-adhered lens mold half which is one of the male and female lens mold halves; (9) removing the embedded hydrogel lens precursor from the lens-adhered lens mold half (preferably before the embedded hydrogel lens precursor is contact with water or any liquid); and (10) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

In accordance with the invention, difference in the concentration of each polymerizable components (materials) between in the first lens-forming composition and in the second lens-forming composition is less than 10%, preferably about 7.5% or less, more preferably about 5.0% or less, even more preferably about 2.5% or less.

Lens-forming compositions (a.k.a., polymerizable compositions) are described in numerous patents and are well known to a person skilled in the art. There are generally two types of lens-forming compositions: the first for forming non-silicone hydrogel contact lenses (i.e., a non-silicone hydrogel bulk material in this application) and the other for forming silicone hydrogel contact lenses (i.e., a silicone hydrogel bulk material in this application).

Typically, a lens-forming composition for forming a non-silicone hydrogel bulk material is either (1) a monomer mixture comprising (a) at least one hydrophilic vinylic monomer (e.g., hydroxyl-containing vinylic monomer, N-vinyl amide monomer, (meth)acrylamido monomer, or combinations thereof), (b) a vinylic crosslinker, and (c) at least one component selected from the group consisting of a hydrophobic vinylic monomer, a free-radical initiator (photoinitiator or thermal initiator), a UV-absorbing vinylic monomer, a high-energy-violet-light ("HEVL") absorbing vinylic monomer, a visibility tinting agent, and combinations thereof; or (2) an aqueous solution comprising one or more water-soluble prepolymers and at least one component selected from the group consisting of hydrophilic vinylic monomer, a vinylic crosslinker, a hydrophobic vinylic monomer, a lubricating agent (or so-called internal wetting agents incorporated in a lens formulation), a free-radical initiator (photoinitiator or thermal initiator), a UV-absorbing vinylic monomer, a HEVL absorbing vinylic monomer, a visibility tinting agent, and combinations thereof.

Examples of water-soluble prepolymers include without limitation: a water-soluble crosslinkable poly(vinyl alcohol) prepolymer described in U.S. Pat. Nos. 5583163 and 6303687; a water-soluble vinyl group-terminated polyurethane prepolymer described in U.S. Pat. No. 6995192; derivatives of a polyvinyl alcohol, polyethyleneimine or polyvinylamine, which are disclosed in U.S. Pat. No. 5849841; a water-soluble crosslinkable polyurea prepolymer described in U.S. Pat. Nos. 6479587 and 7977430; crosslinkable polyacrylamide; crosslinkable statistical copolymers of vinyl lactam, MMA and a comonomer,

which are disclosed in U.S. Pat. No. 5712356; crosslinkable copolymers of vinyl lactam, vinyl acetate and vinyl alcohol, which are disclosed in U.S. Pat. No. 5665840; polyether-polyester copolymers with crosslinkable side chains which are disclosed in U.S. Pat. No. 6492478; branched polyalkylene glycol-urethane prepolymers disclosed in U.S. Pat. No. 6165408; polyalkylene glycol-tetra(meth)acrylate prepolymers disclosed in U.S. Pat. No. 6221303; crosslinkable polyallylamine gluconolactone prepolymers disclosed in U.S. Pat. No. 6472489.

Numerous lens-forming compositions for forming non-silicone hydrogel bulk materials (contact lenses) have been described in numerous patents and patent applications published by the filing date of this application and have been used in producing commercial non-silicone hydrogel contact lenses. Examples of commercial non-silicone hydrogel contact lenses include, without limitation, alafilcon A, acofilcon A, deltafilcon A, etafilcon A, focofilcon A, helfilcon A, helfilcon B, hilafilcon B, hioxifilcon A, hioxifilcon B, hioxifilcon D, methafilcon A, methafilcon B, nelfilcon A, nesofilcon A, ocufilcon A, ocufilcon B, ocufilcon C, ocufilcon D, omafilcon A, phemfilcon A, polymacon, samfilcon A, telfilcon A, tetrafilcon A, and vifilcon A. They can be used as a lens-forming composition of the invention.

Preferably, a lens-forming composition for forming a non-silicone hydrogel bulk material comprises at least 50% by mole of at least one hydroxyl-containing vinylic monomer, preferably selected from the group consisting of hydroxyethyl (meth)acrylate, glycerol (meth)acrylate, 3-hydroxypropyl (meth)acrylate, 2-hydroxypropyl (meth)acrylate, 3-amino-2-hydroxypropyl (meth)acrylate, N-2-hydroxyethyl (meth)acrylamide, N-3-hydroxypropyl (meth)acrylamide, N-2-hydroxypropyl (meth)acrylamide, N-2,3-dihydroxypropyl (meth)acrylamide, N-tris(hydroxymethyl)methyl (meth)acrylamide, vinyl alcohol, allyl alcohol, and combinations thereof, more preferably selected from the group consisting of hydroxyethyl (meth)acrylate, glycerol (meth)acrylate, hydroxyethyl (meth)acrylamide, and vinyl alcohol.

Numerous lens-forming compositions for forming silicone hydrogel contact lenses (bulk materials) have been described in numerous patents and patent applications published by the filing date of this application and have been used in producing commercial SiHy contact lenses. Examples of commercial SiHy contact lenses include, without limitation, asmoofilcon A, balafilcon A, comofilcon A, delefilcon A, efrofilcon A, enfilcon A, fanfilcon A, galyfilcon A, lotrafilcon A, lotrafilcon B, naraofilcon A, naraofilcon B, senofilcon A, senofilcon B, senofilcon C, smaofilcon A, somofilcon A, and stenfilcon A. They can be used as a lens-forming composition of the invention.

In accordance with the invention, a lens-forming composition for forming a silicone hydrogel bulk material comprises (1) at least one polysiloxane vinylic monomer and/or at least one polysiloxane vinylic crosslinker and (2) at least one hydrophilic vinylic monomer.

Any polysiloxane vinylic monomers can be used in the invention. Examples of preferred polysiloxanes vinylic monomers include without limitation: those of formula (M1) which are described later in this application and can be obtained from commercial suppliers (e.g., Shin-Etsu, Gelest, etc.); those prepared according to procedures described in patents, e.g., U.S. Pat. Nos. 5070215, 6166236, 6867245, 8415405, 8475529, 8614261, and 9217813; those prepared by reacting a hydroxyalkyl (meth)acrylate or (meth)acrylamide or a (meth)acryloxypolyethylene glycol with a mono-epoxypropyloxypentyl-terminated polydimethylsiloxane; those prepared by reacting glycidyl (meth)acrylate with a mono-carbinol-terminated polydimethylsiloxane, a mono-aminopropyl-terminated polydimethylsiloxane, or a mono-ethylaminopropyl-terminated polydimethylsiloxane; and those prepared by reacting isocyanatoethyl (meth)acrylate with a mono-carbinol-terminated polydimethylsiloxane according to coupling reactions well known to a person skilled in the art.

Any suitable polysiloxane vinylic crosslinkers can be used in the invention. Examples of preferred polysiloxane vinylic crosslinkers include without limitation: polysiloxane vinylic crosslinkers each comprising hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one H-bond donor (preferably hydroxyl groups); di-(meth)acryloyl-terminated polydimethylsiloxanes; di-vinyl carbonate-terminated polydimethylsiloxanes; di-vinyl carbamate-terminated polydimethylsiloxane; N,N,N',N'-tetrakis(3-methacryloxy-2-hydroxypropyl)-alpha,omega-bis-3-aminopropyl-polydimethylsiloxane; polysiloxane-containing macromer selected from the group consisting of Macromer A, Macromer B, Macromer C, and Macromer D described in US 5,760,100; polysiloxane-containing macromers disclosed in U.S. Pat. Nos. 4136250, 4153641, 4182822, 4189546, 4343927, 4254248, 4355147, 4276402, 4327203, 4341889, 4486577, 4543398, 4605712, 4661575, 4684538, 4703097, 4833218, 4837289, 4954586, 4954587, 5010141, 5034461, 5070170, 5079319, 5039761, 5346946, 5358995, 5387632, 5416132, 5451617, 5486579, 5962548, 5981675, 6039913, and 6762264; polysiloxane-containing macromers disclosed in U.S. Pat. Nos. 4259467, 4260725, and 4261875.

One class of preferred polysiloxane vinylic crosslinkers are di-(meth)acryloyl-terminated polysiloxane vinylic crosslinkers each having dimethylsiloxane units and hydrophilized siloxane units each having one methyl substituent and one monovalent C₄–C₄₀ organic radical substituent having 2 to 6 hydroxyl groups, more preferably a polysiloxane vinylic crosslinker of formula (G), as described later in this application. They can be prepared according to the procedures disclosed in U.S. Pat. No. 10081697.

Another class of preferred polysiloxane vinylic crosslinkers are vinylic crosslinkers each of which comprises one sole polydiorganosiloxane segment and two terminal (meth)acryloyl groups, which can be obtained from commercial suppliers; prepared by

reacting glycidyl (meth)acrylate (meth)acryloyl chloride with a di-amino-terminated polydimethylsiloxane or a di-hydroxyl-terminated polydimethylsiloxane; prepared by reacting isocyanatoethyl (meth)acrylate with di-hydroxyl-terminated polydimethylsiloxanes prepared by reacting an amino-containing acrylic monomer with di-carboxyl-terminated polydimethylsiloxane in the presence of a coupling agent (a carbodiimide); prepared by reacting a carboxyl-containing acrylic monomer with di-amino-terminated polydimethylsiloxane in the presence of a coupling agent (a carbodiimide); or prepared by reacting a hydroxyl-containing acrylic monomer with a di-hydroxy-terminated polydisiloxane in the presence of a diisocyanate or di-epoxy coupling agent.

Other classes of preferred polysiloxane vinylic crosslinkers are chain-extended polysiloxane vinylic crosslinkers each of which has at least two polydiorganosiloxane segments linked by a linker between each pair of polydiorganosiloxane segments and two terminal ethylenically unsaturated groups, which can be prepared according to the procedures described in U.S. Pat. Nos. 5034461, 5416132, 5449729, 5760100, 7423074, 8529057, 8835525, 8993651, 10301451, and 10465047.

Preferably, a lens forming composition for forming a silicone hydrogel bulk material comprises at least one first polysiloxane vinylic crosslinker comprising hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one H-bond donor (preferably hydroxyl groups).

Any hydrophilic vinylic monomers can be used in the invention. Examples of preferred hydrophilic vinylic monomers are alkyl (meth)acrylamides (as described later in this application), hydroxyl-containing acrylic monomers (as described below), amino-containing acrylic monomers (as described later in this application), carboxyl-containing acrylic monomers (as described later in this application), N-vinyl amide monomers (as described later in this application), methylene-containing pyrrolidone monomers (i.e., pyrrolidone derivatives each having a methylene group connected to the pyrrolidone ring at 3- or 5-position) (as described later in this application), acrylic monomers having a C₁-C₄ alkoxyethoxy group (as described later in this application), vinyl ether monomers (as described later in this application), allyl ether monomers (as described later in this application), phosphorylcholine-containing vinylic monomers (as described later in this application), N-2-hydroxyethyl vinyl carbamate, N-carboxyvinyl- β -alanine (VINAL), N-carboxyvinyl- α -alanine, and combinations thereof.

In accordance with the invention, a lens-forming composition for forming a silicone hydrogel bulk material can further comprise at least one silicone-containing vinylic monomer having a bis(trialkylsilyloxy)-alkylsilyl group or a tris(trialkylsilyloxy)silyl group. Examples of such preferred silicone-containing vinylic monomers include without limitation those of formula (M2), which are described later in this application and can be obtained from

commercial suppliers (e.g., Shin-Etsu, Gelest, etc.) or can be prepared according to procedures described in U.S. Pat. Nos. 5070215, 6166236, 7214809, 8475529, 8658748, 9097840, 9103965, and 9475827.

In accordance with the invention, a lens-forming composition for forming a silicone hydrogel bulk material can also comprise one or more hydrophobic non-silicone vinylic monomers. Examples of preferred hydrophobic non-silicone vinylic monomers can be non-silicone hydrophobic acrylic monomers (methyl (meth)acrylate, ethyl (meth)acrylate, propyl (meth)acrylate, isopropyl (meth)acrylate, cyclohexyl (meth)acrylate, 2-ethylhexyl (meth)acrylate, isobornyl (meth)acrylate, (meth)acrylonitrile, etc.), fluorine-containing acrylic monomers (e.g., perfluorohexylethyl-thio-carbonyl-aminoethyl-methacrylate, perfluoro-substituted-C₂-C₁₂ alkyl (meth)acrylates described below, etc.), vinyl alkanoates (e.g., vinyl acetate, vinyl propionate, vinyl butyrate, vinyl valerate, etc.), vinyloxyalkanes (e.g., vinyl ethyl ether, propyl vinyl ether, n-butyl vinyl ether, isoputyl vinyl ether, cyclohexyl vinyl ether, t-butyl vinyl ether, etc.), styrene, vinyl toluene, vinyl chloride, vinylidene chloride, 1-butene, and combinations thereof.

Any suitable perfluoro-substituted-C₂-C₁₂ alkyl (meth)acrylates can be used in the invention. Examples of perfluoro-substituted-C₂-C₁₂ alkyl (meth)acrylates include without limitation 2,2,2-trifluoroethyl (meth)acrylate, tetrafluoropropyl (meth)acrylate, hexafluoro-isopropyl (meth)acrylate, hexafluorobutyl (meth)acrylate, heptafluorobutyl (meth)acrylate, octafluoropentyl (meth)acrylate, heptafluorodecyl (meth)acrylate, pentafluorophenyl (meth)acrylate, and combinations thereof.

In accordance with the invention, a lens-forming composition for forming a silicone hydrogel bulk material can also comprise one or more non-silicone vinylic crosslinkers. Examples of preferred non-silicone vinylic crosslinkers are described later in this application.

In accordance with the invention, a lens-forming composition for forming a silicone hydrogel bulk material can also comprises other polymerizable materials, such as, a UV-absorbing vinylic monomer, a UV/high-energy-violet-light ("HEVL") absorbing vinylic monomer, polymerizable photochromic compound, a polymerizable tinting agent (polymerizable dye), or combinations thereof, as known to a person skilled in the art.

Any suitable UV-absorbing vinylic monomers and UV/HEVL-absorbing vinylic monomers can be used in a polymerizable composition for preparing a preformed SiHy contact lens of the invention. Examples of preferred UV-absorbing and UV/HEVL-absorbing vinylic monomers include without limitation : 2-(2-hydroxy-5-vinylphenyl)-2H-benzotriazole, 2-(2-hydroxy-5-acryloxyphenyl)-2H-benzotriazole, 2-(2-hydroxy-3-methacrylamido methyl-5-tert octylphenyl) benzotriazole, 2-(2'-hydroxy-5'-methacrylamidophenyl)-5-chlorobenzotriazole, 2-(2'-hydroxy-5'-methacrylamidophenyl)-5-methoxybenzotriazole, 2-(2'-hydroxy-5'-methacryloxypropyl-3'-t-butyl-phenyl)-5-chlorobenzotriazole, 2-(2'-hydroxy-5'-

methacryloxypropylphenyl) benzotriazole, 2-hydroxy-5-methoxy-3-(5-(trifluoromethyl)-2H-benzo[d][1,2,3]triazol-2-yl)benzyl methacrylate (WL-1), 2-hydroxy-5-methoxy-3-(5-methoxy-2H-benzo[d][1,2,3]triazol-2-yl)benzyl methacrylate (WL-5), 3-(5-fluoro-2H-benzo[d][1,2,3]triazol-2-yl)-2-hydroxy-5-methoxybenzyl methacrylate (WL-2), 3-(2H-benzo[d][1,2,3]triazol-2-yl)-2-hydroxy-5-methoxybenzyl methacrylate (WL-3), 3-(5-chloro-2H-benzo[d][1,2,3]triazol-2-yl)-2-hydroxy-5-methoxybenzyl methacrylate (WL-4), 2-hydroxy-5-methoxy-3-(5-methyl-2H-benzo[d][1,2,3]triazol-2-yl)benzyl methacrylate (WL-6), 2-hydroxy-5-methyl-3-(5-(trifluoromethyl)-2H-benzo[d][1,2,3]triazol-2-yl)benzyl methacrylate (WL-7), 4-allyl-2-(5-chloro-2H-benzo[d][1,2,3]triazol-2-yl)-6-methoxyphenol (WL-8), 2-{2'-Hydroxy-3'-*tert*-5'[3''-(4''-vinylbenzyloxy)propoxy]phenyl}-5-methoxy-2H-benzotriazole, phenol, 2-(5-chloro-2H-benzotriazol-2-yl)-6-(1,1-dimethylethyl)-4-ethenyl- (UVAM), 2-[2'-hydroxy-5'-(2-methacryloxyethyl)phenyl]-2H-benzotriazole (2-Propenoic acid, 2-methyl-, 2-[3-(2H-benzotriazol-2-yl)-4-hydroxyphenyl]ethyl ester, Norbloc), 2-{2'-Hydroxy-3'-*tert*-butyl-5'-[3'-methacryloyloxypropoxy]phenyl}-2H-benzotriazole, 2-{2'-Hydroxy-3'-*tert*-butyl-5'-[3'-methacryloyloxypropoxy]phenyl}-5-methoxy-2H-benzotriazole (UV13), 2-{2'-Hydroxy-3'-*tert*-butyl-5'-[3'-methacryloyloxypropoxy]phenyl}-5-chloro-2H-benzotriazole (UV28), 2-[2'-Hydroxy-3'-*tert*-butyl-5'-(3'-acryloyloxypropoxy)phenyl]-5-trifluoromethyl-2H-benzotriazole (UV23), 2-(2'-hydroxy-5-methacrylamidophenyl)-5-methoxybenzotriazole (UV6), 2-(3-allyl-2-hydroxy-5-methylphenyl)-2H-benzotriazole (UV9), 2-(2-Hydroxy-3-methallyl-5-methylphenyl)-2H-benzotriazole (UV12), 2-3'-*t*-butyl-2'-hydroxy-5'-(3''-dimethylvinylsilylpropoxy)-2'-hydroxyphenyl)-5-methoxybenzotriazole (UV15), 2-(2'-hydroxy-5'-methacryloylpropyl-3'-*tert*-butylphenyl)-5-methoxy-2H-benzotriazole (UV16), 2-(2'-hydroxy-5'-acryloylpropyl-3'-*tert*-butylphenyl)-5-methoxy-2H-benzotriazole (UV16A), 2-Methylacrylic acid 3-[3-*tert*-butyl-5-(5-chlorobenzotriazol-2-yl)-4-hydroxyphenyl]-propyl ester (16-100, CAS#96478-15-8), 2-(3-(*tert*-butyl)-4-hydroxy-5-(5-methoxy-2H-benzo[d][1,2,3]triazol-2-yl)phenoxy)ethyl methacrylate (16-102); Phenol, 2-(5-chloro-2H-benzotriazol-2-yl)-6-methoxy-4-(2-propen-1-yl) (CAS#1260141-20-5); 2-[2-Hydroxy-5-[3-(methacryloyloxy)propyl]-3-*tert*-butylphenyl]-5-chloro-2H-benzotriazole; Phenol, 2-(5-ethenyl-2H-benzotriazol-2-yl)-4-methyl-, homopolymer (9CI) (CAS#83063-87-0). In accordance with the invention, the polymerizable composition comprises about 0.1% to about 3.0%, preferably about 0.2% to about 2.5%, more preferably about 0.3% to about 2.0%, by weight of one or more UV-absorbing vinylic monomers, related to the amount of all polymerizable components in the polymerizable composition.

Examples of preferred photochromic vinylic monomers include polymerizable naphthopyrans, polymerizable benzopyrans, polymerizable indenonaphthopyrans, polymerizable phenanthropyrans, polymerizable spiro(benzindoline)-naphthopyrans, polymerizable spiro(indoline)benzopyrans, polymerizable spiro(indoline)-naphthopyrans, polymerizable spiro(indoline)quinopyrans, polymerizable spiro(indoline)-pyrans,

polymerizable naphthoxazines, polymerizable spirobenzopyrans; polymerizable spirobenzopyrans, polymerizable spirobenzothiopyrans, polymerizable naphthacenediones, polymerizable spirooxazines, polymerizable spiro(indoline)naphthoxazines, polymerizable spiro(indoline)pyridobenzoxazines, polymerizable spiro(benzindoline)pyridobenzoxazines, polymerizable spiro(benzindoline)naphthoxazines, polymerizable spiro(indoline)-benzoxazines, polymerizable diarylethenes, and combinations thereof, as disclosed in U.S. Pat. Nos. 4929693, 5166345 6017121, 7556750, 7584630, 7999989, 8158037, 8697770, 8741188, 9052438, 9097916, 9465234, 9904074, 10197707, 6019914, 6113814, 6149841, 6296785, and 6348604.

In accordance with the invention, the formed silicone hydrogel bulk material has an equilibrium water content (i.e., in fully hydrated state or when being fully hydrated) of from about 20% to about 70% (preferably from about 20% to about 65%, more preferably from about 25% to about 65%, even more preferably from about 30% to about 60%) by weight, an oxygen permeability of at least about 40 barrers (preferably at least about 60 barrers, more preferably at least about 80 barrers, more preferably at least about 100 barrers), and a modulus (i.e., Young's modulus) of about 1.5 MPa or less (preferably from about 0.2 MPa to about 1.2 MPa, more preferably from about 0.3 MPa to about 1.1 MPa, even more preferably from about 0.4 MPa to about 1.0 MPa).

Lens-forming compositions of the invention can be prepared by dissolving or blending all of the desirable components (or materials) in any suitable non-reactive diluent, so long as that the first lens-forming composition obtained is more viscous than the second lens-forming composition obtained.

A non-reactive diluent for preparing the first lens-forming composition can be any diluent having a high viscosity (e.g., greater than 20 cP at 20°C). Preferred examples of such non-reactive diluents includes without limitation a poly(C₂-C₄ alkyleneoxide) polymer, glycerol, propylene glycol, diethylene glycol, or mixtures thereof.

In accordance with the invention, a poly(C₂-C₄ alkyleneoxide) polymer refers to a polymer of T₁-(EO)_{m1}(PO)_{n1}(BO)_{p1}-T₂ in which: T₁ and T₂ independent of each other is hydrogen, hydroxyl, C₁-C₄ alkoxy, or a C₁-C₄ alkyl; EO is a divalent radical of ethyleneoxide

($\text{---CH}_2\text{---CH}_2\text{---O---}$); PO is a divalent radical of propyleneoxide ($\text{---CH}_2\text{---}\overset{\text{CH}_3}{\underset{|}{\text{CH}}}\text{---O---}$); BO is a

divalent radical of butyleneoxide ($\text{---CH}_2\text{---}\overset{\text{C}_2\text{H}_5}{\underset{|}{\text{CH}}}\text{---O---}$); m₁ is zero or an integer of from 5 to 65; n₁ is zero or an integer of from 5 to 52; p₁ is zero or integer of from 5 to 30; wherein if n₁ is not zero, p₁ is zero; wherein if p₁ is not zero, n₁ is zero and m₁ is not zero; wherein (m₁+n₁+p₁) is a value to provide the poly(C₂-C₄ alkyleneoxide) polymer with a number average molecular weight of from about 300 to about 3000 Daltons (preferably from about

400 to about 2500 Daltons, more preferably from about 400 to about 2000 Daltons, even more preferably from about 400 to about 1500 Daltons).

Examples of preferred poly(C₂-C₄ alkyleneoxide) polymers includes poly(ethyleneoxide) ("PEO"), poly(propyleneoxide) ("PPO"), poly(ethyleneoxide)-poly(propyleneoxide) di-block copolymer ("PEO-PPO"), poly(ethyleneoxide)-poly(propyleneoxide)-poly(ethyleneoxide) tri-block copolymer ("PEO-PPO-PEO"), poly(propyleneoxide)-poly(ethyleneoxide)-poly(propyleneoxide) tri-block copolymer ("PPO-PEO-PPO"), poly(ethyleneoxide)-poly(butyleneoxide) di-block copolymer ("PEO-PBO"), poly(ethyleneoxide)-poly(butyleneoxide)-poly(ethyleneoxide) tri-block copolymer ("PEO-PBO-PEO"), poly(butyleneoxide)-poly(ethyleneoxide)-poly(butyleneoxide) tri-block copolymer ("PBO-PEO-PBO"), and mixtures thereof. Those preferred poly(C₂-C₄ alkyleneoxide) polymers, such as PEO, PPO, PEO-PPO, PEO-PPO-PEO and PPO-PEO-PPO, can be obtained from commercial sources or synthesized according to known methods. PEO-PBO, PEO-PBO-PEO and PBO-PEO-PBO can be synthesized according to procedures described in U.S. Pat. No. 8318144.

A non-reactive diluent for preparing the second lens-forming composition can be any diluent having a low viscosity, preferably less than 5 cP at 20°C. Examples of such non-reactive diluents include without limitation tetrahydrofuran, dipropylene glycol methyl ether, ethylene glycol n-butyl ether, ketones (e.g., acetone, methyl ethyl ketone, etc.), diethylene glycol n-butyl ether, diethylene glycol methyl ether, propylene glycol methyl ether, propylene glycol methyl ether acetate, dipropylene glycol methyl ether acetate, propylene glycol n-propyl ether, dipropylene glycol n-propyl ether, tripropylene glycol n-butyl ether, propylene glycol n-butyl ether, dipropylene glycol n-butyl ether, dipropylene glycol dimethyl ether, ethyl acetate, butyl acetate, amyl acetate, methyl lactate, ethyl lactate, i-propyl lactate, methylene chloride, 2-butanol, 1-propanol, 2-propanol, menthol, cyclohexanol, cyclopentanol, 2-pentanol, 3-pentanol, 2-hexanol, 3-hexanol, 3-methyl-2-butanol, tert-butanol, tert-amyl alcohol, 2-methyl-2-pentanol, 2,3-dimethyl-2-butanol, 3-methyl-3-pentanol, 1-methylcyclohexanol, 2-methyl-2-hexanol, 3-methyl-3-hexanol, 2,4-dimethyl-2-pentanol, 1-methylcyclopentanol, 1-ethylcyclopentanol, 1-ethylcyclopentanol, 1-ethoxy-2-propanol, 1-methyl-2-propanol, t-amyl alcohol, isopropanol, and mixtures thereof. More preferred organic solvents include without limitation 1-propanol, isopropanol, sec-butanol, tert-butyl alcohol, tert-amyl alcohol, methyl ethyl ketone, methyl isopropyl ketone, methyl propyl ketone, ethyl acetate, dipropylene glycol methyl ether, ethylene glycol n-butyl ether, diethylene glycol n-butyl ether, diethylene glycol methyl ether, propylene glycol methyl ether, propylene glycol methyl ether acetate, dipropylene glycol methyl ether acetate, propylene glycol n-propyl ether, dipropylene glycol n-propyl ether, propylene glycol n-butyl ether, dipropylene glycol n-butyl ether, dipropylene glycol dimethyl ether, and mixtures thereof.

Mold halves for making contact lenses (or inserts) are well known to a person skilled in the art and, for example, are employed in cast molding. In general, a molding assembly comprises at least two mold halves, one male half and one female mold half. The male mold half has a first molding (or optical) surface which is in direct contact with a polymerizable composition for cast molding of a contact lens (or an insert) and defines the posterior (back) surface of a molded contact lens (or a molded insert); and the female mold half has a second molding (or optical) surface which is in direct contact with the polymerizable composition and defines the anterior (front) surface of the molded contact lens (or molded insert). The male and female mold halves are configured to receive each other such that a lens- or insert-forming cavity is formed between the first molding surface and the second molding surface.

Methods of manufacturing mold halves for cast-molding a contact lens or an insert are generally well known to those of ordinary skill in the art. The process of the present invention is not limited to any particular method of forming a mold half. In fact, any method of forming a mold half can be used in the present invention. The mold halves can be formed through various techniques, such as injection molding or lathing. Examples of suitable processes for forming the mold halves are disclosed in U.S. Pat. Nos. 4444711; 4460534; 5843346; and 5894002.

Virtually all materials known in the art for making mold halves can be used to make mold halves for making contact lenses or inserts. For example, polymeric materials, such as polyethylene, polypropylene, polystyrene, PMMA, Topas® COC grade 8007-S10 (clear amorphous copolymer of ethylene and norbornene, from Ticona GmbH of Frankfurt, Germany and Summit, New Jersey), or the like can be used.

In accordance with the invention, an insert is made of any plastic material.

In a preferred embodiment, an insert is made of a hard plastics (preferably a crosslinked polymethylmethacrylate), e.g., any one known to a person skilled in the art.

In another preferred embodiment, an insert is made of a crosslinked silicone polymer (or a silicone rubber or elastomer as known to a person skilled in the art), e.g., any one known to a person skilled in the art. A crosslinked silicone material has three-dimensional polymer networks (i.e., polymer matrix), is insoluble in water, and has an equilibrium water content of about 5% or less, preferably about 3% or less, more preferably about 2% or less) by weight (i.e., in fully-hydrated state).

In another preferred embodiment, an insert is made of a non-silicone hydrogel material (any one of those described later in this application or known to a person skilled in the art).

In another preferred embodiment, an insert is made of a silicone hydrogel material (any one of those described later in this application or known to a person skilled in the art).

In another preferred embodiment, an insert is made of a rigid gas permeable material (e.g., a material made from fluorosilicone acrylates or known to a person skilled in the art).

In another preferred embodiment, an insert comprises repeating units of at least one polymerizable photochromic compound (i.e., at least one photochromic vinylic monomer), at least one UV-absorbing vinylic monomer, at least one UV/HEVL-absorbing vinylic monomer, a fluorescent vinylic monomer, or combinations thereof.

In another preferred embodiment, an insert comprises at least one photochromic dye or pigment, at least one color-filtering material for correcting color blindness, a diffractive material, a high refractive-index material, or combinations.

In another preferred embodiment, an insert is made of a hydrophobic crosslinked acrylic material that has an equilibrium water content of less than 5% by weight and comprises at least about 55% (preferably at least about 60%, more preferably at least about 65% even more preferably at least about 70%) by mole of repeating units of one or more acrylic monomers and/or one or more acrylic crosslinker or crosslinking agent and at least about 6% by mole (preferably at least about 8% by mole, more preferably at least about 10% by mole, even more preferably at least about 12% by mole) of repeating units at least one vinylic crosslinking agent.

Any hydrophobic acrylic monomers can be used in forming a hydrophobic material of the inventions. Examples of hydrophobic acrylic monomers includes silicone-containing acrylic monomers (any one of those described below in this application), non-silicone hydrophobic acrylic monomers (any one of those described below in this application), fluorine-containing acrylic monomers (any one of those described below in this application), aryl acrylic monomers (any one of those described below in this application), and combinations thereof.

An aryl acrylic monomer refers to an acrylic monomer comprising at least one aryl moiety.

It is also understood that any hydrophobic vinylic monomer can be used as a substitute for a hydrophobic acrylic monomer, so long as it comprises at least one H-bond acceptor such as ester bond, amide bond, carbonate bond, carbamate bond, ether bond, or combinations thereof. Examples of such hydrophobic monomers include vinyl alkanoates (any one of those described above in this application), vinyloxyalkanes (any one of those described above in this application), and combinations thereof.

It is understood that the mole percentages of each of the components of the hydrophobic crosslinked acrylic material can be obtained based on the mole percentages of its corresponding polymerizable component (material) in an insert-forming composition for making the insert.

In accordance with the invention, a hydrophobic crosslinked acrylic material

comprises repeating units of at least one vinylic crosslinking agent. Any suitable vinyl crosslinking agents can be used in the invention. Examples of preferred vinylic cross-linking agents include without limitation: acrylic crosslinking agents (crosslinkers) (any one of those described later in this application), allyl methacrylate, allyl acrylate, an aryl crosslinking agent (e.g., divinylbenzene, 2-methyl-1,4-divinylbenzene, bis(4-vinylphenyl)methane, 1,2-bis(4-vinylphenyl)ethane, etc.), triallyl isocyanurate, 2,4,6-triallyloxy-1,3,5-triazine, 1,2,4-trivinylcyclohexane, or combinations thereof. It is understood that vinylic crosslinking agents are required for imparting the desired rigidity to the crosslinked polymeric material of the rigid hydrophobic insert.

In a preferred embodiment, the hydrophobic crosslinked acrylic material comprises repeating units of at least one acrylic crosslinking agent (any one of those described later in this application).

In another preferred embodiment, the hydrophobic crosslinked acrylic material comprises repeating units of at least one aryl crosslinking agent (any one of those described later in this application).

In another preferred embodiment, the hydrophobic crosslinked acrylic material comprises repeating units of at least one vinyl-functional polysiloxane that comprises at least two vinyl groups each directly attached to one silicon atom and at least 15% by mole of siloxane units each having at least one phenyl substituent.

Examples of such vinyl functional polysiloxanes include without limitation vinyl terminated polyphenylmethysiloxanes (e.g., PMV9925 from Gelest), vinylphenylmethyl terminated phenylmethyl-vinylphenylsiloxane copolymer (e.g., PVV-3522 from Gelest), vinyl terminated diphenylsiloxane-dimethylsiloxane copolymers (e.g., PDV-1625 from Gelest), or combinations thereof. Preferably, the vinyl-functional polysiloxane is vinyl terminated polyphenylmethysiloxanes (e.g., PMV9925 from Gelest), vinylphenylmethyl terminated phenylmethyl-vinylphenylsiloxane copolymer (e.g., PVV-3522 from Gelest), or combinations thereof.

In accordance with the invention, an insert of the invention can be prepared by cast-molding of an insert-forming composition (i.e., a polymerizable composition) in insert molds.

In accordance with the invention, the female insert mold half has, in its molding surface, depressions that will in turn define the alignment features.

An insert-forming composition can be prepared by mixing all polymerizable materials as described above in the desired proportions, together with one or more polymerization initiators (thermal polymerization initiators or photoinitiators) in the presence or preferably in the absence of a non-reactive organic solvent (i.e., a non-reactive diluent) as described later in this application.

Any thermal polymerization initiators can be used in the invention. Suitable thermal

polymerization initiators are known to the skilled artisan and comprise, for example peroxides, hydroperoxides, azo-bis(alkyl- or cycloalkylnitriles), persulfates, percarbonates, or mixtures thereof. Examples of preferred thermal polymerization initiators include without limitation benzoyl peroxide, t-butyl peroxide, t-amyl peroxybenzoate, 2,2-bis(tert-butylperoxy)butane, 1,1-bis(tert-butylperoxy)cyclohexane, 2,5-Bis(tert-butylperoxy)-2,5-dimethylhexane, 2,5-bis(tert-butylperoxy)-2,5-dimethyl-3-hexyne, bis(1-(tert-butylperoxy)-1-methylethyl)benzene, 1,1-bis(tert-butylperoxy)-3,3,5-trimethylcyclohexane, di-t-butyl-diperoxyphthalate, t-butyl hydroperoxide, t-butyl peracetate, t-butyl peroxybenzoate, t-butylperoxy isopropyl carbonate, acetyl peroxide, lauroyl peroxide, decanoyl peroxide, dicetyl peroxydicarbonate, di(4-t-butylcyclohexyl)peroxy dicarbonate (Perkadox 16S), di(2-ethylhexyl)peroxy dicarbonate, t-butylperoxy pivalate (Lupersol 11); t-butylperoxy-2-ethylhexanoate (Trigonox 21-C50), 2,4-pentanedione peroxide, dicumyl peroxide, peracetic acid, potassium persulfate, sodium persulfate, ammonium persulfate, 2,2'-azobis(4-methoxy-2,4-dimethylvaleronitrile) (VAZO 33), 2,2'-Azobis[2-(2-imidazolin-2-yl)propane]dihydrochloride (VAZO 44), 2,2'-azobis(2-amidinopropane) dihydrochloride (VAZO 50), 2,2'-azobis(2,4-dimethylvaleronitrile) (VAZO 52), 2,2'-azobis(isobutyronitrile) (VAZO 64 or AIBN), 2,2'-azobis-2-methylbutyronitrile (VAZO 67), 1,1-azobis(1-cyclohexanecarbonitrile) (VAZO 88); 2,2'-azobis(2-cyclopropylpropionitrile), 2,2'-azobis(methylisobutyrate), 4,4'-Azobis(4-cyanovaleric acid), and combinations thereof. Preferably, the thermal initiator is 2,2'-azobis(isobutyronitrile) (AIBN or VAZO 64).

Suitable photoinitiators are benzoin methyl ether, diethoxyacetophenone, a benzoylphosphine oxide, 1-hydroxycyclohexyl phenyl ketone and Darocur and Irgacur types, preferably Darocur 1173® and Darocur 2959®, Germanium-based Norrish Type I photoinitiators (e.g., those described in US7605190). Examples of benzoylphosphine initiators include 2,4,6-trimethylbenzoyldiphenylphosphine oxide; bis-(2,6-dichlorobenzoyl)-4-N-propylphenyl-phosphine oxide; and bis-(2,6-dichlorobenzoyl)-4-N-butylphenylphosphine oxide. Reactive photoinitiators which can be incorporated, e.g., into a macromer or can be used as a special monomer are also suitable. Examples of reactive photoinitiators are those disclosed in EP632329.

In accordance with the invention, from about 1 to about 20 μL (preferably from about 1 to about 15 μL , more preferably from about 1 to about 10 μL , even more preferably from about 2 to about 6 μL) of the first lens-forming composition is deposited in the center of the first molding surface of the female lens mold half, according to any technique known to a person skilled in the art.

In accordance with the invention, the insert is placed on top of the first lens-forming composition on the first molding surface of the female lens mold half in a way to ensure that the third central axis coincides with the first central axis and the insert is held at a position

above the first molding surface of the female lens mold half, according to any techniques known to a person skilled in the art. Examples of preferred systems for insert placement and positioning includes without limitation those described in co-pending U.S. patent application No. 63/283,718 filed 29 November 2021 entitled "SYSTEMS AND METHODS FOR INSERT PLACEMENT TO FABRICATE HYBRID CONTACT LENSES".

The second lens-forming composition can be introduced into the insert-molding cavity and the lens-molding cavity respectively according to any techniques known to a person skilled in the art.

The curing of the lens-forming compositions within lens-molding cavity of a mold can be carried out thermally (i.e., by heating) or actinically (i.e., by actinic radiation, e.g., UV radiation and/or visible radiation) to activate the polymerization initiators.

The actinic polymerization of the polymerizable composition in a mold can be carried out by irradiating the closed mold with the polymerizable composition therein with an UV or visible light, according to any techniques known to a person skilled in the art.

The thermal polymerization of the polymerizable composition in a mold can be carried out conveniently in an oven at a temperature of from 25 to 120°C and preferably 40 to 100°C, as well known to a person skilled in the art. The reaction time may vary within wide limits, but is conveniently, for example, from 1 to 24 hours or preferably from 2 to 12 hours. It is advantageous to previously degas the silicone-hydrogel-lens-forming composition and to carry out said copolymerization reaction under an inert atmosphere, e.g., under N₂ or Ar atmosphere.

After the curing step, the steps of opening a mold (i.e., separating the male lens mold half from the female lens mold half with the embedded silicone hydrogel lens precursor attached onto one of the male and female lens mold halves) and delensing (i.e., removing the embedded silicone hydrogel lens precursor from the lens-adhered lens mold half) are carried out according to any techniques known to a person skilled in the art.

After the embedded hydrogel lens precursor is delensed, it typically is extracted with an extraction medium as well known to a person skilled in the art. The extraction liquid medium is any solvent capable of dissolving the diluent(s), unpolymerized polymerizable materials, and oligomers in the embedded silicone hydrogel lens precursor. Water, any organic solvents known to a person skilled in the art, or a mixture thereof can be used in the invention. Preferably, the organic solvents used extraction liquid medium are water, a buffered saline, a C₁-C₃ alkyl alcohol, 1,2-propylene glycol, a polyethyleneglycol having a number average molecular weight of about 400 Daltons or less, a C₁-C₆ alkylalcohol, or combinations thereof.

The extracted embedded hydrogel contact lens can then be hydrated according to any method known to a person skilled in the art.

The hydrated embedded hydrogel contact lens can further subject to further processes, such as, for example, surface treatment, packaging in lens packages with a packaging solution which is well known to a person skilled in the art; sterilization such as autoclave at from 118 to 124°C for at least about 30 minutes; and the like.

Lens packages (or containers) are well known to a person skilled in the art for autoclaving and storing a soft contact lens. Any lens packages can be used in the invention. Preferably, a lens package is a blister package which comprises a base and a cover, wherein the cover is detachably sealed to the base, wherein the base includes a cavity for receiving a sterile packaging solution and the contact lens.

Lenses are packaged in individual packages, sealed, and sterilized (e.g., by autoclave at about 120°C or higher for at least 30 minutes under pressure) prior to dispensing to users. A person skilled in the art will understand well how to seal and sterilize lens packages.

Although various embodiments of the invention have been described using specific terms, devices, and methods, such description is for illustrative purposes only. The words used are words of description rather than of limitation. As would be obvious to one skilled in the art, many variations and modifications of the invention may be made by those skilled in the art without departing from the spirit and scope of the novel concepts of the disclosure. In addition, it should be understood that aspects of the various embodiments of the invention may be interchanged either in whole or in part or can be combined in any manner and/or used together, as illustrated below:

1. A method for producing embedded hydrogel contact lenses, comprising the steps of:
 - (1) obtaining a first lens-forming composition and a second lens-forming composition, wherein the first and second lens-forming compositions comprise identical polymerizable components (materials) but different non-reactive diluents, wherein the first lens-forming composition comprises a first non-reactive diluent and the second lens-forming composition comprises a second non-reactive diluent, wherein difference (ΔC_i) in the concentration of each polymerizable components (materials) between in the first lens-forming composition and in the second lens-forming composition is less than 10.0%, wherein $\Delta C_i = \frac{|C_{2i} - C_{1i}|}{C_{2i}} \times 100\%$ in which C_{1i} and C_{2i} are the concentrations of polymerizable component i in the first and second lens-forming compositions respectively, wherein ratio of the viscosity of the first lens-forming composition over the viscosity of the second lens-forming composition is at least 1.5;
 - (2) obtaining a lens mold, wherein the lens mold comprises a female lens mold half and

- a male lens mold half, wherein the female lens mold half has a first molding surface and a first central axis, wherein the male lens mold half has a second molding surface and a second central axis, wherein the first molding surface defines the anterior surface of an embedded hydrogel contact lens, wherein the second molding surface defines the posterior surface of the embedded hydrogel contact lens, wherein the female and male lens mold halves are configured to receive each other such that a mold cavity is formed between the first and second molding surfaces when the mold is closed;
- (3) obtaining an insert which is made of a polymeric material and comprises a front surface, an opposite back surface, a third central axis, and a diameter up to about 13.0 mm;
 - (4) dosing from about 1 to about 20 μL of the first lens-forming composition in the center of the first molding surface of the female lens mold half;
 - (5) placing the insert on top of the first lens-forming composition on the first molding surface of the female lens mold half in a way to ensure that the third central axis coincides with the first central axis and the insert is held at a position above the first molding surface of the female lens mold half;
 - (6) placing the male lens mold half on top of the female lens mold half and closing the male and female lens mold halves to form a molding assembly comprising the first and second lens-forming compositions and the insert immersed therein in the molding assembly;
 - (7) curing the first and second lens-forming compositions in the molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the first and second lens-forming compositions and the insert embedded in the bulk hydrogel material and centered in the embedded hydrogel lens precursor;
 - (8) separating the lens mold obtained in step (7) into the male and female lens mold halves, with the embedded hydrogel lens precursor adhered on a lens-adhered lens mold half which is one of the male and female lens mold halves;
 - (9) removing the embedded hydrogel lens precursor from the lens-adhered lens mold half (preferably before the embedded hydrogel lens precursor is contact with water or any liquid); and
 - (10) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.
2. The method of embodiment 1, wherein the step of (8) curing the lens-forming composition is carried out actinically by using UV and/or visible light.

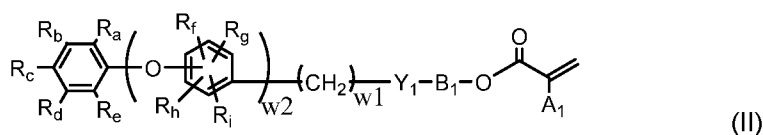
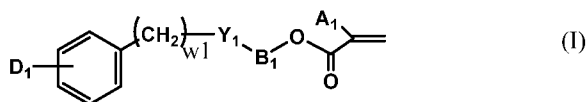
3. The method of embodiment 1, wherein the step of (8) curing the lens-forming composition is carried out thermally by heating the first molding assembly in an oven at one or more curing temperatures selected from about 40°C to about 100°C.
4. The method of any one of embodiments 1 to 3, wherein ratio of the viscosity of the first lens-forming composition over the viscosity of the second lens-forming composition is at least 2.0.
5. The method of any one of embodiments 1 to 3, wherein ratio of the viscosity of the first lens-forming composition over the viscosity of the second lens-forming composition is at least 2.5.
6. The method of any one of embodiments 1 to 3, wherein ratio of the viscosity of the first lens-forming composition over the viscosity of the second lens-forming composition is at least 3.0.
7. The method of any one of embodiments 1 to 6, wherein from about 1 to about 15 μL of the first lens-forming composition is dosed in the center of the first molding surface of the female lens mold half.
8. The method of any one of embodiments 1 to 6, wherein from about 1 to about 10 μL of the first lens-forming composition is dosed in the center of the first molding surface of the female lens mold half.
9. The method of any one of embodiments 1 to 6, wherein from about 2 to about 6 μL of the first lens-forming composition is dosed in the center of the first molding surface of the female lens mold half.
10. The method of any one of embodiments 1 to 9, wherein the difference (ΔC_i) in the concentration of each polymerizable components (materials) between in the first lens-forming composition and in the second lens-forming composition is about 7.5% or less.
11. The method of any one of embodiments 1 to 9, wherein the difference (ΔC_i) in the concentration of each polymerizable components (materials) between in the first lens-forming composition and in the second lens-forming composition is about 5.0% or less.
12. The method of any one of embodiments 1 to 9, wherein the difference (ΔC_i) in the concentration of each polymerizable components (materials) between in the first lens-forming composition and in the second lens-forming composition is about 2.5% or less.
13. The method of any one of embodiments 1 to 12, wherein the first non-reactive diluent has a viscosity of greater than 20 cP at 20°C.
14. The method of any one of embodiments 1 to 12, wherein the first non-reactive diluent has a viscosity of greater than 30 cP at 20°C.
15. The method of any one of embodiments 1 to 12, wherein the first non-reactive diluent has a viscosity of greater than 40 cP at 20°C.
16. The method of any one of embodiments 1 to 12, wherein the first non-reactive diluent

- has a viscosity of greater than 50 cP at 20°C.
17. The method of any one of embodiments 1 to 16, wherein the first non-reactive diluent is a poly(C₂-C₄ alkyleneoxide) polymer, glycerol, propylene glycol, diethylene glycol, or mixtures thereof.
 18. The method of any one of embodiments 1 to 16, wherein the first non-reactive diluent is a poly(C₂-C₄ alkyleneoxide) polymer with a number average molecular weight of from about 300 to about 3000 Daltons.
 19. The method of any one of embodiments 1 to 16, wherein the first non-reactive diluent is a poly(C₂-C₄ alkyleneoxide) polymer with a number average molecular weight of from about 400 to about 2500 Daltons.
 20. The method of any one of embodiments 1 to 16, wherein the first non-reactive diluent is a poly(C₂-C₄ alkyleneoxide) polymer with a number average molecular weight of from about 400 to about 2000 Daltons.
 21. The method of any one of embodiments 1 to 16, wherein the first non-reactive diluent is a poly(C₂-C₄ alkyleneoxide) polymer with a number average molecular weight of from about 400 to about 1500 Daltons.
 22. The method of any one of embodiments 1 to 20, wherein the first non-reactive diluent is a poly(ethyleneoxide) ("PEO"), poly(propyleneoxide) ("PPO"), poly(ethyleneoxide)-poly(propyleneoxide) di-block copolymer ("PEO-PPO"), poly(ethyleneoxide)-poly(propyleneoxide)-poly(ethyleneoxide) tri-block copolymer ("PEO-PPO-PEO"), poly(propyleneoxide)-poly(ethyleneoxide)-poly(propyleneoxide) tri-block copolymer ("PPO-PEO-PPO"), or mixtures thereof.
 23. The method of any one of embodiments 1 to 22, wherein the first non-reactive diluent has a viscosity of less than 5 cP at 20°C.
 24. The method of any one of embodiments 1 to 23, wherein the first non-reactive diluent is dipropylene glycol methyl ether, ethylene glycol n-butyl ether, acetone, methyl ethyl ketone, diethylene glycol n-butyl ether, diethylene glycol methyl ether, propylene glycol methyl ether, propylene glycol methyl ether acetate, dipropylene glycol methyl ether acetate, propylene glycol n-propyl ether, dipropylene glycol n-propyl ether, tripropylene glycol n-butyl ether, propylene glycol n-butyl ether, dipropylene glycol n-butyl ether, dipropylene glycol dimethyl ether, ethyl acetate, butyl acetate, amyl acetate, methyl lactate, ethyl lactate, i-propyl lactate, methylene chloride, 2-butanol, 1-propanol, 2-propanol, menthol, cyclohexanol, cyclopentanol, 2-pentanol, 3-pentanol, 2-hexanol, 3-hexanol, 3-methyl-2-butanol, tert-butanol, tert-amyl alcohol, 2-methyl-2-pentanol, 2,3-dimethyl-2-butanol, 3-methyl-3-pentanol, 1-methylcyclohexanol, 2-methyl-2-hexanol, 3-methyl-3-hexanol, 2,4-dimethyl-2-pentanol, 1-methylcyclopentanol, 1-ethylcyclopentanol, 1-ethylcyclopentanol, 1-ethoxy-2-propanol, 1-methyl-2-propanol, t-

- amyl alcohol, isopropanol, or mixtures thereof.
25. The method of any one of embodiments 1 to 23, wherein the first non-reactive diluent is 1-propanol, isopropanol, sec-butanol, tert-butyl alcohol, tert-amyl alcohol, methyl ethyl ketone, methyl isopropyl ketone, methyl propyl ketone, ethyl acetate, dipropylene glycol methyl ether, ethylene glycol n-butyl ether, diethylene glycol n-butyl ether, diethylene glycol methyl ether, propylene glycol methyl ether, propylene glycol methyl ether acetate, dipropylene glycol methyl ether acetate, propylene glycol n-propyl ether, dipropylene glycol n-propyl ether, propylene glycol n-butyl ether, dipropylene glycol n-butyl ether, dipropylene glycol dimethyl ether, or mixtures thereof.
 26. The method of any one of embodiments 1 to 25, wherein the polymeric material of the insert comprises repeating units of at least one polymerizable photochromic compound (i.e., photochromic vinylic monomer), at least one UV-absorbing vinylic monomer, at least one UV/HEVL-absorbing vinylic monomer, at least one fluorescent vinylic monomer, or combinations thereof.
 27. The method of any one of embodiments 1 to 26, wherein the insert comprises at least one color-filtering material for correcting color blindness, a diffractive material, a high refractive-index material, or combinations.
 28. The method of any one of embodiments 1 to 27, wherein the polymeric material of the insert is a hard plastics.
 29. The method of embodiment 28, wherein the hard plastics is a crosslinked polymethylmethacrylate.
 30. The method of any one of embodiments 1 to 27, wherein the polymeric material of the insert is a crosslinked silicone polymer that has three-dimensional polymer networks, is insoluble in water, and has an equilibrium water content of about 5% or less by weight.
 31. The method of embodiment 30, wherein the crosslinked silicone polymer has an equilibrium water content of about 3% or less (preferably about 2% or less) by weight.
 32. The method of any one of embodiments 1 to 27, wherein the polymeric material of the insert is a rigid gas permeable material.
 33. The method of any one of embodiments 1 to 27, wherein the polymeric material of the insert is a hydrophobic crosslinked acrylic material that has an equilibrium water content of less than 5% by weight and comprises at least 55% by mole of repeating units of one or more acrylic monomers and/or one or more acrylic crosslinker and at least about 6% by mole of repeating units of at least one vinylic crosslinking agent.
 34. The method of embodiment 33, wherein the hydrophobic crosslinked acrylic material has an equilibrium water content of about 4% or less by weight.
 35. The method of embodiment 33, wherein the hydrophobic crosslinked acrylic material has an equilibrium water content of about 3% or less by weight.

36. The method of embodiment 33, wherein the hydrophobic crosslinked acrylic material has an equilibrium water content of about 2% or less by weight.
37. The method of any one of embodiments 33 to 36, wherein the hydrophobic crosslinked acrylic material comprises at least about 60% by mole of repeating units of said one or more acrylic monomers and/or said one or more acrylic crosslinker.
38. The method of any one of embodiments 33 to 36, wherein the hydrophobic crosslinked acrylic material comprises at least about 70% by mole of repeating units of said one or more acrylic monomers and/or said one or more acrylic crosslinker.
39. The method of any one of embodiments 33 to 36, wherein the hydrophobic crosslinked acrylic material comprises at least about 80% by mole of repeating units of said one or more acrylic monomers and/or said one or more acrylic crosslinker.
40. The method of any one of embodiments 33 to 39, wherein the crosslinked polymeric material comprises at least about 25% by mole of repeating units of said at least one vinylic crosslinking agent.
41. The method of any one of embodiments 33 to 39, wherein the hydrophobic crosslinked acrylic material comprises at least about 30% by mole of repeating units of said at least one vinylic crosslinking agent.
42. The method of any one of embodiments 33 to 39, wherein the hydrophobic crosslinked acrylic material comprises at least about 35% by mole of repeating units of said at least one vinylic crosslinking agent.
43. The method of any one of embodiments 33 to 42, wherein said at least one vinylic crosslinking agent comprises at least one acrylic crosslinking agent.
44. The method of embodiment 43, wherein said at least one acrylic crosslinking agent is ethylene glycol dimethacrylate; ethylene glycol diacrylate; 1,3-propanediol diacrylate; 1,3-propanediol dimethacrylate; 2,3-propanediol diacrylate; 2,3-propanediol dimethacrylate; 1,4-butanediol dimethacrylate; 1,4-butanediol diacrylate; 1,5-pentanediol dimethacrylate; 1,5-pentanediol diacrylate; 1,6-hexanediol dimethacrylate; 1,6-hexanediol diacrylate; diethylene glycol dimethacrylate; diethylene glycol diacrylate; triethylene glycol dimethacrylate; triethylene glycol diacrylate; tetraethylene glycol dimethacrylate; tetraethylene glycol diacrylate; N,N'-methylene bis(acrylamide); N,N'-methylene bis(methacrylamide); N,N'-ethylene bis(acrylamide); N,N'-ethylene bis(methacrylamide); N,N'-hexamethylene bisacrylamide; N,N'-hexamethylene bismethacrylamide; pentaerythritol triacrylate, pentaerythritol trimethacrylate, trimethyloxypropane triacrylate, trimethyloxypropane trimethacrylate, tris(2-hydroxyethyl)isocyanurate triacrylate, tris(2-hydroxyethyl)isocyanurate trimethacrylate, 1,3,5-triacryloylhexahydro-1,3,5-triazine, 1,3,5-trimethacryloylhexahydro-1,3,5-triazine; pentaerythritol tetraacrylate, pentaerythritol tetramethacrylate,

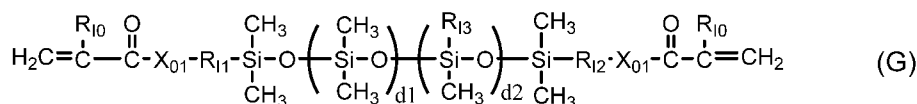
- di(trimethyloxypropane) tetraacrylate, di(trimethyloxypropane) tetramethacrylate, or combinations thereof.
45. The method of embodiment 43, wherein said at least one acrylic crosslinking agent is allyl (meth)acrylate, pentaerythritol tetra(meth)acrylate, Neopentyl glycol di(meth)acrylate, an aryl crosslinking agent, triallyl isocyanurate, 2,4,6-triallyloxy-1,3,5-triazine, 1,2,4-trivinylcyclohexane, or combinations thereof.
 46. The method of any one of embodiments 33 to 45, wherein said at least one vinylic crosslinking agent comprises divinylbenzene, 2-methyl-1,4-divinylbenzene, bis(4-vinylphenyl)methane, 1,2-bis(4-vinylphenyl)ethane, or combinations thereof.
 47. The method of any one of embodiments 33 to 46, wherein the hydrophobic crosslinked acrylic material comprises repeating units of at least one silicone-containing acrylic monomer.
 48. The method of any one of embodiments 33 to 47, wherein the hydrophobic crosslinked acrylic material comprises repeating units of at least one fluorine-containing acrylic monomer.
 49. The method of embodiment 48, wherein said at least one fluorine-containing acrylic monomer is perfluorohexylethyl-thio-carbonyl-aminoethyl-methacrylate, 2,2,2-trifluoroethyl (meth)acrylate, tetrafluoropropyl (meth)acrylate, hexafluoro-iso-propyl (meth)acrylate, hexafluorobutyl (meth)acrylate, heptafluorobutyl (meth)acrylate, octafluoropentyl (meth)acrylate, heptafluorodecyl (meth)acrylate, pentafluorophenyl (meth)acrylate, or combinations thereof.
 50. The method of any one of embodiments 33 to 49, wherein the hydrophobic crosslinked acrylic material comprises repeating units of at least one polysiloxane vinylic crosslinker.
 51. The method of any one of embodiments 33 to 50, wherein the hydrophobic crosslinked acrylic material comprises repeating units of at least one aryl acrylic monomer of formula (I) or (II)



wherein A₁ is H or CH₃ (preferably H); B₁ is (CH₂)_{m1} or [O(CH₂)₂]_{z1} in which m₁ is 2-6 and z₁ is 1-10; Y₁ is a direct bond, O, S, or NR' in which R' is H, CH₃, C_nH_{2n+1} in which n'=1-10, iso-OC₃H₇, C₆H₅, or CH₂C₆H₅; R_a, R_b, R_c, R_d, R_e, R_f, R_g, R_h, and R_i independent of one another are H, C₁-C₁₂ alkyl, or C₁-C₁₂ alkoxy (preferably all are H);

- w₁ is 0-6, provided that m₁+w₁≤8; w₂ is an integer from 1 to 3; and D₁ is H, Cl, Br, C₁-C₄ alkyl, C₁-C₄ alkoxy, C₆H₅, or CH₂C₆H₅.
52. The method of embodiment 51, wherein said at least one aryl acrylic monomer comprises at least one vinylic monomer selected from the group consisting of 2-ethylphenoxy acrylate; 2-ethylphenoxy methacrylate; phenyl acrylate; phenyl methacrylate; benzyl acrylate; benzyl methacrylate; 2-phenylethyl acrylate; 2-phenylethyl methacrylate; 3-phenylpropyl acrylate; 3-phenylpropyl methacrylate; 4-phenylbutyl acrylate; 4-phenylbutyl methacrylate; 4-methylphenyl acrylate; 4-methylphenyl methacrylate; 4-methylbenzyl acrylate; 4-methylbenzyl methacrylate; 2-(2-methylphenyl)ethyl acrylate; 2-(2-methylphenyl)ethyl methacrylate; 2-(3-methylphenyl)ethyl acrylate; 2-(3-methylphenyl)ethyl methacrylate; 2-(4-methylphenyl)ethyl acrylate; 2-(4-methylphenyl)ethyl methacrylate; 2-(4-propylphenyl)ethyl acrylate; 2-(4-propylphenyl)ethyl methacrylate; 2-(4-(1-methylethyl)phenyl)ethyl acrylate; 2-(4-(1-methylethyl)phenyl)ethyl methacrylate; 2-(4-methoxyphenyl)ethyl acrylate; 2-(4-methoxyphenyl)ethyl methacrylate; 2-(4-cyclohexylphenyl)ethyl acrylate; 2-(4-cyclohexylphenyl)ethyl methacrylate; 2-(2-chlorophenyl)ethyl acrylate; 2-(2-chlorophenyl)ethyl methacrylate; 2-(3-chlorophenyl)ethyl acrylate; 2-(3-chlorophenyl)ethyl methacrylate; 2-(4-chlorophenyl)ethyl acrylate; 2-(4-chlorophenyl)ethyl methacrylate; 2-(4-bromophenyl)ethyl acrylate; 2-(4-bromophenyl)ethyl methacrylate; 2-(3-phenylphenyl)ethyl acrylate; 2-(3-phenylphenyl)ethyl methacrylate; 2-(4-phenylphenyl)ethyl acrylate; 2-(4-phenylphenyl)ethyl methacrylate; 2-(4-benzylphenyl)ethyl acrylate; 2-(4-benzylphenyl)ethyl methacrylate; 2-(phenylthio)ethyl acrylate; 2-(phenylthio)ethyl methacrylate; 2-benzyloxyethyl acrylate; 3-benzyloxypropyl acrylate; 2-benzyloxyethyl methacrylate; 3-benzyloxypropyl methacrylate; 2-[2-(benzyloxy)ethoxy]ethyl acrylate; 2-[2-(benzyloxy)ethoxy]ethyl methacrylate, and combinations thereof.
 53. The method of any one of embodiments 33 to 52, wherein the hydrophobic crosslinked acrylic material comprises repeating units of at least one hydrophobic vinylic monomer selected from the group consisting of a vinyl alkanoate, a vinyloxyalkane, styrene, vinyl toluene, vinyl chloride, vinylidene chloride, 1-butene, and combinations thereof.
 54. The method of any one of embodiments 33 to 53, wherein the hydrophobic insert is rigid.
 55. The method of any one of embodiments 1 to 54, wherein the first and second lens-forming compositions comprises at least 50% by mole of at least one hydroxyl-containing vinylic monomer.
 56. The method of embodiment 55, wherein said at least one hydroxyl-containing vinylic

- monomer is selected from the group consisting of hydroxyethyl (meth)acrylate, glycerol (meth)acrylate, 3-hydroxypropyl (meth)acrylate, 2-hydroxypropyl (meth)acrylate, 3-amino-2-hydroxypropyl (meth)acrylate, N-2-hydroxyethyl (meth)acrylamide, N-3-hydroxypropyl (meth)acrylamide, N-2-hydroxypropyl (meth)acrylamide, N-2,3-dihydroxypropyl (meth)acrylamide, N-tris(hydroxymethyl)methyl (meth)acrylamide, vinyl alcohol, allyl alcohol, and combinations thereof.
57. The method of any one of embodiments 1 to 54, wherein the first and second lens-forming compositions comprise (a) at least one polysiloxane vinylic monomer and/or at least one first polysiloxane vinylic crosslinker and (b) at least one hydrophilic vinylic monomer.
 58. The method of embodiment 57, wherein the first and second lens-forming compositions comprise at least one hydrophilized polysiloxane vinylic crosslinker comprising hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one H-bond donor.
 59. The method of embodiment 58, wherein said at least one hydrophilized polysiloxane vinylic crosslinker comprises hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one hydroxyl groups.
 60. The method of embodiment 58 or 59, wherein said at least one hydrophilized polysiloxane vinylic crosslinker comprises a di-(meth)acryloyloxy-terminated polysiloxane vinylic crosslinker having dimethylsiloxane units and hydrophilized siloxane units each having one methyl substituent and one monovalent C₄–C₄₀ organic radical substituent having 2 to 6 hydroxyl groups.
 61. The method of any one of embodiments 58 to 60, wherein said at least one hydrophilized polysiloxane vinylic crosslinker comprises a vinylic crosslinker of formula (G)



in which:

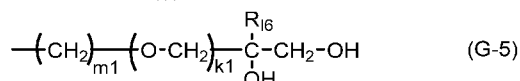
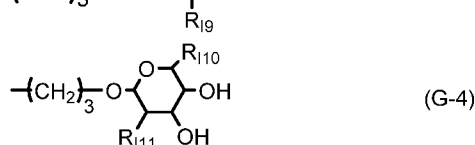
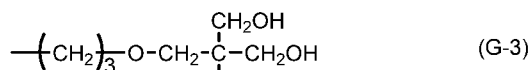
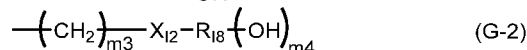
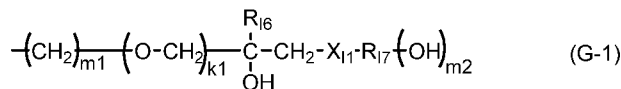
d1 is an integer of from 30 to 500 and d2 is an integer of from 1 to 75, provided that d2/d1 is from about 0.035 to about 0.15;

X₀₁ is O or NR_{IN} in which R_{IN} is hydrogen or C₁–C₁₀-alkyl;

R₁₀ is hydrogen or methyl;

R₁₁ and R₁₂ independently of each other are a substituted or unsubstituted C₁–C₁₀ alkylene divalent radical or a divalent radical of –R₁₄–O–R₁₅– in which R₁₄ and R₁₅ independently of each other are a substituted or unsubstituted C₁–C₁₀ alkylene divalent radical;

R₁₃ is a monovalent radical of any one of formula (G-1) to (G-5)



k₁ is zero or 1; m₁ is an integer of 2 to 4; m₂ is an integer of 1 to 5; m₃ is an integer of 3 to 6; m₄ is an integer of 2 to 5;

R₁₆ is hydrogen or methyl;

R₁₇ is a C₂-C₆ hydrocarbon radical having (m₂+1) valencies;

R₁₈ is a C₂-C₆ hydrocarbon radical having (m₄+1) valencies;

R₁₉ is ethyl or hydroxymethyl;

R₁₀ is methyl or hydromethyl;

R₁₁₁ is hydroxyl or methoxy;

X₁₁ is a sulfur linkage of ---S--- or a tertiary amino linkage of $\text{---NR}_{112}\text{---}$ in which R₁₁₂ is C₁-C₁ alkyl, hydroxyethyl, hydroxypropyl, or 2,3-dihydroxypropyl; and

X₁₂ is an amide linkage of $\text{---NR}_{113}\text{---}\overset{\text{O}}{\underset{\text{O}}{\text{C}}}\text{---}$ or $\text{---}\overset{\text{O}}{\underset{\text{O}}{\text{C}}}\text{---NR}_{113}\text{---}$ in which R₁₁₃ is hydrogen or C₁-C₁₀ alkyl.

62. The method of any one of embodiments 57 to 61, wherein the first and second lens-forming compositions comprise: a di-(meth)acryloyl-terminated polydimethylsiloxane, a di-vinyl carbonate-terminated polydimethylsiloxane; a di-vinyl carbamate-terminated polydimethylsiloxane; N,N,N',N'-tetrakis(3-methacryloxy-2-hydroxypropyl)-alpha,omega-bis-3-aminopropyl-polydimethylsiloxane, or a combination thereof.
63. The method of any one of embodiments 57 to 62, wherein the first and second lens-forming compositions comprise: (1) a vinylic crosslinker which comprises one sole polydiorganosiloxane segment and two terminal ethylenically-unsaturated groups selected from the group consisting of (meth)acryloyloxy groups, (meth)acryloylamino groups, vinyl carbonate groups, vinylcarbamate groups; and/or (2) a chain-extended polysiloxane vinylic crosslinker which comprises at least two polydiorganosiloxane segment and a covalent linker between each pair of polydiorganosiloxane segments and two two terminal ethylenically-unsaturated groups selected from the group

- consisting of (meth)acryloyloxy groups, (meth)acryloylamino groups, vinyl carbonate groups, vinylcarbamate groups.
64. The method of any one of embodiments 57 to 62, wherein the first and second lens-forming compositions comprise: α,ω -bis[3-(meth)acrylamidopropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxyethoxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxypropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxy-isopropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxybutyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidoethoxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidopropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidoisopropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidobutyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxyethylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxypropylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxybutylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acrylamidoethylamino-2-hydroxypropyloxy-propyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidopropylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamide-butylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyloxy-ethoxypropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyl-N-ethylaminopropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyl-aminopropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyloxy-(polyethylenoxy)propyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxyethylamino-carbonyloxy-ethoxypropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxyethylamino-carbonyloxy-(polyethylenoxy)propyl]-terminated polydimethylsiloxane, or combinations thereof.
65. The method of any one of embodiments 57 to 64, wherein said at least one hydrophilic vinylic monomer comprises: (1) an alkyl (meth)acrylamide selected from the group consisting of (meth)acrylamide, N,N-dimethyl (meth)acrylamide, N-ethyl (meth)acrylamide, N,N-diethyl (meth)acrylamide, N-propyl (meth)acrylamide, N-isopropyl (meth)acrylamide, N-3-methoxypropyl (meth)acrylamide, and combinations

thereof; (2) a hydroxyl-containing acrylic monomer selected from the group consisting of N-2-hydroxyethyl (meth)acrylamide, N,N-bis(hydroxyethyl) (meth)acrylamide, N-3-hydroxypropyl (meth)acrylamide, N-2-hydroxypropyl (meth)acrylamide, N-2,3-dihydroxypropyl (meth)acrylamide, N-tris(hydroxymethyl)methyl (meth)acrylamide, 2-hydroxyethyl (meth)acrylate, 3-hydroxypropyl (meth)acrylate, 2-hydroxypropyl (meth)acrylate, glycerol methacrylate (GMA), di(ethylene glycol) (meth)acrylate, tri(ethylene glycol) (meth)acrylate, tetra(ethylene glycol) (meth)acrylate, poly(ethylene glycol) (meth)acrylate having a number average molecular weight of up to 1500, poly(ethylene glycol)ethyl (meth)acrylamide having a number average molecular weight of up to 1500, and combinations thereof; (3) a carboxyl-containing acrylic monomer selected from the group consisting of 2-(meth)acrylamidoglycolic acid, (meth)acrylic acid, ethylacrylic acid, 3-(meth)acrylamidopropionic acid, 5-(meth)acrylamidopentanoic acid, 4-(meth)acrylamidobutanoic acid, 3-(meth)acrylamido-2-methylbutanoic acid, 3-(meth)acrylamido-3-methylbutanoic acid, 2-(meth)acrylamido-2methyl—3,3-dimethyl butanoic acid, 3-(meth)acrylamidohexanoic acid, 4-(meth)acrylamido-3,3-dimethylhexanoic acid, and combinations thereof; (4) an amino-containing acrylic monomer selected from the group consisting of N-2-aminoethyl (meth)acrylamide, N-2-methylaminoethyl (meth)acrylamide, N-2-ethylaminoethyl (meth)acrylamide, N-2-dimethylaminoethyl (meth)acrylamide, N-3-aminopropyl (meth)acrylamide, N-3-methylaminopropyl (meth)acrylamide, N-3-dimethylaminopropyl (meth)acrylamide, 2-aminoethyl (meth)acrylate, 2-methylaminoethyl (meth)acrylate, 2-ethylaminoethyl (meth)acrylate, 3-aminopropyl (meth)acrylate, 3-methylaminopropyl (meth)acrylate, 3-ethylaminopropyl (meth)acrylate, 3-amino-2-hydroxypropyl (meth)acrylate, trimethylammonium 2-hydroxy propyl (meth)acrylate hydrochloride, dimethylaminoethyl (meth)acrylate, and combinations thereof; (5) an N-vinyl amide monomer selected from the group consisting of N-vinylpyrrolidone (*aka*, N-vinyl-2-pyrrolidone), N-vinyl-3-methyl-2-pyrrolidone, N-vinyl-4-methyl-2-pyrrolidone, N-vinyl-5-methyl-2-pyrrolidone, N-vinyl-6-methyl-2-pyrrolidone, N-vinyl-3-ethyl-2-pyrrolidone, N-vinyl-4,5-dimethyl-2-pyrrolidone, N-vinyl-5,5-dimethyl-2-pyrrolidone, N-vinyl-3,3,5-trimethyl-2-pyrrolidone, N-vinyl piperidone (*aka*, N-vinyl-2-piperidone), N-vinyl-3-methyl-2-piperidone, N-vinyl-4-methyl-2-piperidone, N-vinyl-5-methyl-2-piperidone, N-vinyl-6-methyl-2-piperidone, N-vinyl-6-ethyl-2-piperidone, N-vinyl-3,5-dimethyl-2-piperidone, N-vinyl-4,4-dimethyl-2-piperidone, N-vinyl caprolactam (*aka*, N-vinyl-2-caprolactam), N-vinyl-3-methyl-2-caprolactam, N-vinyl-4-methyl-2-caprolactam, N-vinyl-7-methyl-2-caprolactam, N-vinyl-7-ethyl-2-caprolactam, N-vinyl-3,5-dimethyl-2-caprolactam, N-vinyl-4,6-dimethyl-2-caprolactam, N-vinyl-3,5,7-trimethyl-2-caprolactam, N-vinyl-N-methyl acetamide, N-

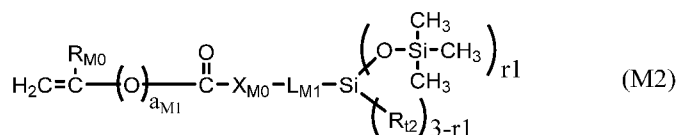
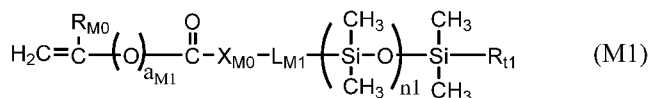
vinyl formamide, N-vinyl acetamide, N-vinyl isopropylamide, N-vinyl-N-ethyl acetamide, N-vinyl-N-ethyl formamide, and mixtures thereof; (6) a methylene-containing pyrrolidone monomer selected from the group consisting of 1-methyl-3-methylene-2-pyrrolidone, 1-ethyl-3-methylene-2-pyrrolidone, 1-methyl-5-methylene-2-pyrrolidone, 1-ethyl-5-methylene-2-pyrrolidone, 5-methyl-3-methylene-2-pyrrolidone, 5-ethyl-3-methylene-2-pyrrolidone, 1-n-propyl-3-methylene-2-pyrrolidone, 1-n-propyl-5-methylene-2-pyrrolidone, 1-isopropyl-3-methylene-2-pyrrolidone, 1-isopropyl-5-methylene-2-pyrrolidone, 1-n-butyl-3-methylene-2-pyrrolidone, 1-tert-butyl-3-methylene-2-pyrrolidone, and combinations thereof; (7) an acrylic monomer having a C₁-C₄ alkoxyethoxy group and selected from the group consisting of ethylene glycol methyl ether (meth)acrylate, di(ethylene glycol) methyl ether (meth)acrylate, tri(ethylene glycol) methyl ether (meth)acrylate, tetra(ethylene glycol) methyl ether (meth)acrylate, C₁-C₄-alkoxy poly(ethylene glycol) (meth)acrylate having a number average molecular weight of up to 1500, methoxy-poly(ethylene glycol)ethyl (meth)acrylamide having a number average molecular weight of up to 1500, and combinations thereof; (8) a vinyl ether monomer selected from the group consisting of ethylene glycol monovinyl ether, di(ethylene glycol) monovinyl ether, tri(ethylene glycol) monovinyl ether, tetra(ethylene glycol) monovinyl ether, poly(ethylene glycol) monovinyl ether, ethylene glycol methyl vinyl ether, di(ethylene glycol) methyl vinyl ether, tri(ethylene glycol) methyl vinyl ether, tetra(ethylene glycol) methyl vinyl ether, poly(ethylene glycol) methyl vinyl ether, and combinations thereof; (9) an allyl ether monomer selected from the group consisting of ethylene glycol monoallyl ether, di(ethylene glycol) monoallyl ether, tri(ethylene glycol) monoallyl ether, tetra(ethylene glycol) monoallyl ether, poly(ethylene glycol) monoallyl ether, ethylene glycol methyl allyl ether, di(ethylene glycol) methyl allyl ether, tri(ethylene glycol) methyl allyl ether, tetra(ethylene glycol) methyl allyl ether, poly(ethylene glycol) methyl allyl ether, and combinations thereof; (10) a phosphorylcholine-containing vinylic monomer selected from the group consisting of (meth)acryloyloxyethyl phosphorylcholine, (meth)acryloyloxypropyl phosphorylcholine, 4-((meth)acryloyloxy)butyl-2'-(trimethylammonio)ethylphosphate, 2-[(meth)acryloylamino]ethyl-2'-(trimethylammonio)-ethylphosphate, 3-[(meth)acryloylamino]propyl-2'-(trimethylammonio)ethylphosphate, 4-[(meth)acryloylamino]butyl-2'-(trimethylammonio)ethylphosphate, 5-((meth)acryloyloxy)pentyl-2'-(trimethylammonio)ethyl phosphate, 6-((meth)acryloyloxy)hexyl-2'-(triethylammonio)-ethylphosphate, 2-((meth)acryloyloxy)ethyl-2'-(triethylammonio)ethylphosphate, 2-((meth)acryloyloxy)ethyl-2'-(tripropylammonio)ethylphosphate, 2-((meth)acryloyloxy)ethyl-2'-(tributylammonio)ethyl phosphate, 2-

- ((meth)acryloyloxy)propyl-2'-(trimethylammonio)-ethylphosphate, 2-((meth)acryloyloxy)butyl-2'-(trimethylammonio)ethylphosphate, 2-((meth)acryloyloxy)pentyl-2'-(trimethylammonio)ethylphosphate, 2-((meth)acryloyloxy)hexyl-2'-(trimethylammonio)ethyl phosphate, 2-(vinylloxy)ethyl-2'-(trimethylammonio)ethylphosphate, 2-(allyloxy)ethyl-2'-(trimethylammonio)ethylphosphate, 2-(vinylloxycarbonyl)ethyl-2'-(trimethylammonio)ethyl phosphate, 2-(allyloxycarbonyl)ethyl-2'-(trimethylammonio)-ethylphosphate, 2-(vinylcarbonylamino)ethyl-2'-(trimethylammonio)ethylphosphate, 2-(allyloxycarbonylamino)ethyl-2'-(trimethylammonio)ethyl phosphate, 2-(butenoyloxy)ethyl-2'-(trimethylammonio)ethylphosphate, and combinations thereof; (11) allyl alcohol; (12) N-2-hydroxyethyl vinyl carbamate; (13) N-carboxyvinyl- β -alanine (VINAL); (14) N-carboxyvinyl- α -alanine; (15) or combinations thereof.
66. The method of any one of embodiments 57 to 64, wherein said at least one hydrophilic vinylic monomer comprises N-vinylpyrrolidone, N-vinyl-N-methyl acetamide, or combinations thereof.
67. The method of any one of embodiments 57 to 66, wherein said at least one hydrophilic vinylic monomer comprises at least one (meth)acrylamido monomer selected from the group consisting of (meth)acrylamide, N,N-dimethyl (meth)acrylamide, N-ethyl (meth)acrylamide, N,N-diethyl (meth)acrylamide, N-propyl (meth)acrylamide, N-isopropyl (meth)acrylamide, N-3-methoxypropyl (meth)acrylamide, N-2-hydroxyethyl (meth)acrylamide, N,N-bis(hydroxyethyl) (meth)acrylamide, N-3-hydroxypropyl (meth)acrylamide, N-2-hydroxypropyl (meth)acrylamide, N-2,3-dihydroxypropyl (meth)acrylamide, N-tris(hydroxymethyl)methyl (meth)acrylamide, 2-(meth)acrylamidoglycolic acid, 3-(meth)acrylamidopropionic acid, 5-(meth)acrylamidopentanoic acid, 4-(meth)acrylamidobutanoic acid, 3-(meth)acrylamido-2-methylbutanoic acid, 3-(meth)acrylamido-3-methylbutanoic acid, 2-(meth)acrylamido-2-methyl-3,3-dimethyl butanoic acid, 3-(meth)acrylamidohexanoic acid, 4-(meth)acrylamido-3,3-dimethylhexanoic acid, N-2-aminoethyl (meth)acrylamide, N-2-methylaminoethyl (meth)acrylamide, N-2-ethylaminoethyl (meth)acrylamide, N-2-dimethylaminoethyl (meth)acrylamide, N-3-aminopropyl (meth)acrylamide, N-3-methylaminopropyl (meth)acrylamide, N-3-dimethylaminopropyl (meth)acrylamide, methoxy-poly(ethylene glycol)ethyl (meth)acrylamide having a number average molecular weight of up to 1500, and combinations thereof.
68. The method of any one of embodiments 57 to 66, wherein said at least one hydrophilic vinylic monomer comprises (meth)acrylamide, N,N-dimethyl (meth)acrylamide, N-ethyl (meth)acrylamide, N,N-diethyl (meth)acrylamide, N-propyl (meth)acrylamide, N-isopropyl (meth)acrylamide, N-3-methoxypropyl (meth)acrylamide, N-2-hydroxyethyl

- (meth)acrylamide, or combinations thereof.
69. The method of any one of embodiments 57 to 68, wherein said at least one hydrophilic vinylic monomer comprises 2-hydroxyethyl (meth)acrylate, 3-hydroxypropyl (meth)acrylate, 2-hydroxypropyl (meth)acrylate, glycerol methacrylate (GMA), di(ethylene glycol) (meth)acrylate, tri(ethylene glycol) (meth)acrylate, tetra(ethylene glycol) (meth)acrylate, poly(ethylene glycol) (meth)acrylate having a number average molecular weight of up to 1500, or combinations thereof.
70. The method of any one of embodiments 57 to 69, wherein the first and second lens-forming compositions comprise at least one polysiloxane vinylic monomer selected from the group consisting of α -(meth)acryloxypropyl terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -(meth)acryloxy-2-hydroxypropyloxypropyl terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -(2-hydroxyl-methacryloxypropyloxypropyl)- ω -C₁-C₄-alkyl-decamethylpentasiloxane, α -[3-(meth)acryloxyethoxy-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[3-(meth)acryloxy-propyloxy-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[3-(meth)acryloxyisopropyloxy-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[3-(meth)acryloxybutyloxy-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[3-(meth)acryloxyethylamino-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[3-(meth)acryloxypropylamino-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[3-(meth)acryloxy-butylamino-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -(meth)acryloxy(polyethylenoxy)-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[(meth)acryloxy-2-hydroxypropyloxy-ethoxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[(meth)acryloxy-2-hydroxypropyl-N-ethylaminopropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[(meth)acryloxy-2-hydroxypropyl-aminopropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[(meth)acryloxy-2-hydroxypropyloxy-(polyethylenoxy)propyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -(meth)acryloylamidopropyloxypropyl terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -N-methyl-(meth)acryloylamidopropyloxypropyl terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[3-(meth)acrylamidoethoxy-2-hydroxypropyloxy-propyl]-terminated ω -C₁-C₄-alkyl polydimethylsiloxane, α -[3-(meth)acrylamidopropyloxy-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[3-(meth)acrylamidoisopropyloxy-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl

terminated polydimethylsiloxane, α -[3-(meth)acrylamidobutyloxy-2-hydroxypropyloxypropyl]-terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, α -[3-(meth)acryloylamido-2-hydroxypropyloxypropyl] terminated ω -C₁-C₄-alkyl polydimethylsiloxane, α -[3-[N-methyl-(meth)acryloylamido]-2-hydroxypropyloxypropyl] terminated ω -C₁-C₄-alkyl terminated polydimethylsiloxane, N-methyl-N'-(propyltetra(dimethylsiloxy)dimethylbutylsilane) (meth)acrylamide, N-(2,3-dihydroxypropane)-N'-(propyltetra(dimethylsiloxy)dimethylbutylsilane) (meth)acrylamide, (meth)acryloylamidopropyltetra(dimethylsiloxy)dimethylbutylsilane, α -vinyl carbonate-terminated ω -C₁-C₄-alkyl-terminated polydimethylsiloxanes, α -vinyl carbamate-terminated ω -C₁-C₄-alkyl-terminated polydimethylsiloxane, or a mixture thereof.

71. The method of any one of embodiments 57 to 70, wherein the first and second lens-forming compositions comprise at least one silicone-containing vinylic monomer selected from the group consisting of a vinylic monomer having a bis(trialkylsilyloxy)alkylsilyl group, a vinylic monomer having a tris(trialkylsilyloxy)silyl group, a polysiloxane vinylic monomer, 3-methacryloxy propylpentamethyldisiloxane, t-butyltrimethylsiloxyethyl vinyl carbonate, trimethylsilylethyl vinyl carbonate, and trimethylsilylmethyl vinyl carbonate, and combinations thereof.
72. The method of any one of embodiments 57 to 70, wherein the first and second lens-forming compositions comprise at least one silicone-containing vinylic monomer of formula (M1) or (M2)



in which: a_{M1} is zero or 1; R_{M0} is H or methyl; X_{M0} is O or NR_{M1} ; L_{M1} is a C₂-C₈ alkylene divalent radical or a divalent radical of $-\text{L}_{\text{M1}}'-\text{X}_{\text{M1}}-\text{L}_{\text{M1}}''-$, $-(\text{C}_2\text{H}_4\text{O})_{\text{v1}}-\text{CONH}-\text{L}_{\text{M1}}''-$, $-(\text{C}_2\text{H}_4\text{O})_{\text{v1}}-\text{L}_{\text{M1}}''-$, $-\text{L}_{\text{M1}}'-\text{NHCOO}-(\text{C}_2\text{H}_4\text{O})_{\text{v1}}-\text{L}_{\text{M1}}''-$, $-\text{CH}_2-\text{CH}(\text{OH})-\text{CH}_2-\text{X}_{\text{M1}}'-(\text{C}_2\text{H}_4\text{O})_{\text{v2}}-\text{L}_{\text{M1}}''-$, $-\text{L}_{\text{M1}}'-\text{X}_{\text{M1}}'-\text{CH}_2-\text{CH}(\text{OH})-\text{CH}_2-\text{O}-\text{L}_{\text{M1}}''-$, or $-(\text{C}_2\text{H}_4\text{O})_{\text{v1}}-\text{CH}_2-\text{CH}(\text{OH})-\text{CH}_2-\text{O}-\text{L}_{\text{M1}}''-$; L_{M1}' is a C₂-C₈ alkylene divalent radical which has zero or one hydroxyl group; L_{M1}'' is C₃-C₈ alkylene divalent radical which has zero or one hydroxyl group; X_{M1} is O, NR_{M1} , NHCOO , OCONH , CONR_{M1} , or $\text{NR}_{\text{M1}}\text{CO}$; R_{M1} is H or a C₁-C₄ alkyl having 0 to 2 hydroxyl group; R_{t1} and R_{t2} independent of each other are a C₁-C₆ alkyl; X_{M1}' is O or

- NR₁; v₁ is an integer of 1 to 30; m₂ is an integer of 0 to 30; n₁ is an integer of 3 to 40; and r₁ is an integer of 2 or 3.
73. The method of any one of embodiments 57 to 72, wherein the first and second lens-forming compositions comprise tris(trimethylsilyloxy)silylpropyl (meth)acrylate, [3-(meth)acryloxy-2-hydroxypropyloxy]propylbis(trimethylsiloxy)methylsilane, [3-(meth)acryloxy-2-hydroxypropyloxy]propylbis(trimethylsiloxy)butylsilane, 3-(meth)acryloxy-2-(2-hydroxyethoxy)-propyloxy)propylbis(trimethylsiloxy)methylsilane, 3-(meth)acryloxy-2-hydroxypropyloxy)propyltris(trimethylsiloxy)silane, N-[tris(trimethylsiloxy)silylpropyl]-(meth)acrylamide, N-(2-hydroxy-3-(3-(bis(trimethylsilyloxy)methylsilyl)propyloxy)propyl)-2-methyl (meth)acrylamide, N-(2-hydroxy-3-(3-(bis(trimethylsilyloxy)methylsilyl)propyloxy)-propyl) (meth)acrylamide, N-(2-hydroxy-3-(3-(tris(trimethylsilyloxy)silyl)propyloxy)propyl)-2-methyl (meth)acrylamide, N-(2-hydroxy-3-(3-(tris(trimethylsilyloxy)silyl)propyloxy)propyl) (meth)acrylamide, N-[tris(dimethylpropylsiloxy)silylpropyl]-(meth)acrylamide, N-[tris(dimethylphenylsiloxy)silylpropyl] (meth)acrylamide, N-[tris(dimethylethylsiloxy)silylpropyl] (meth)acrylamide, N,N-bis[2-hydroxy-3-(3-(bis(trimethylsilyloxy)methylsilyl)-propyloxy)propyl]-2-methyl (meth)acrylamide, N,N-bis[2-hydroxy-3-(3-(bis(trimethylsilyloxy)methylsilyl)propyloxy)-propyl] (meth)acrylamide, N,N-bis[2-hydroxy-3-(3-(tris(trimethylsilyloxy)silyl)propyloxy)-propyl]-2-methyl (meth)acrylamide, N,N-bis[2-hydroxy-3-(3-(tris(trimethylsilyloxy)silyl)propyloxy)propyl] (meth)acrylamide, N-[2-hydroxy-3-(3-(t-butyltrimethylsilyl)propyloxy)-propyl]-2-methyl (meth)acrylamide, N-[2-hydroxy-3-(3-(t-butyltrimethylsilyl)propyloxy)-propyl] (meth)acrylamide, N,N-bis[2-hydroxy-3-(3-(t-butyltrimethylsilyl)propyloxy)propyl]-2-methyl (meth)acrylamide, N-2-(meth)acryloxyethyl-O-(methyl-bis(trimethylsiloxy-3-propyl)silyl carbamate, 3-(trimethylsilyl)propylvinyl carbonate, 3-(vinylloxycarbonylthio)-propyl-tris(trimethylsiloxy)silane, 3-[tris(trimethylsiloxy)silyl]propylvinyl carbamate, 3-[tris(trimethylsiloxy)silyl] propyl allyl carbamate, 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbonate, or a combination thereof.
74. The method of any one of embodiments 57 to 73, wherein the first and second lens-forming compositions comprise at least one non-silicone vinylic cross-linking agent.
75. The method of embodiment 74, wherein said at least one non-silicone vinylic crosslinking agent comprises ethyleneglycol di-(meth)acrylate, diethyleneglycol di-(meth)acrylate, triethyleneglycol di-(meth)acrylate, tetraethyleneglycol di-(meth)acrylate, glycerol di-(meth)acrylate, 1,3-propanediol di-(meth)acrylate, 1,3-butanediol di-(meth)acrylate, 1,4-butanediol di-(meth)acrylate, glycerol 1,3-diglycerolate di-(meth)acrylate, ethylenebis[oxy(2-hydroxypropane-1,3-diyl)] di-(meth)acrylate, bis[2-(meth)acryloxyethyl] phosphate, trimethylolpropane di-(meth)acrylate, and 3,4-

- bis[(meth)acryloyl]tetrahydrofuran, diacrylamide, dimethacrylamide, N,N-di(meth)acryloyl-N-methylamine, N,N-di(meth)acryloyl-N-ethylamine, N,N'-methylene bis(meth)acrylamide, N,N'-ethylene bis(meth)acrylamide, N,N'-dihydroxyethylene bis(meth)acrylamide, N,N'-propylene bis(meth)acrylamide, N,N'-2-hydroxypropylene bis(meth)acrylamide, N,N'-2,3-dihydroxybutylene bis(meth)acrylamide, 1,3-bis(meth)acrylamidepropane-2-yl dihydrogen phosphate, piperazine diacrylamide, tetraethyleneglycol divinyl ether, triethyleneglycol divinyl ether, diethyleneglycol divinyl ether, ethyleneglycol divinyl ether, triallyl isocyanurate, triallyl cyanurate, trimethylopropane trimethacrylate, pentaerythritol tetramethacrylate, bisphenol A dimethacrylate, allylmethacrylate, allylacrylate, N-allyl-methacrylamide, N-allyl-acrylamide, or combinations thereof.
76. The method of any one of embodiments 57 to 75, wherein the first and second lens-forming compositions comprise at least one blending vinylic monomer.
 77. The method of embodiment 76, wherein said at least one blending vinylic monomer comprises C₁-C₁₀ alkyl (meth)acrylate, cyclopentylacrylate, cyclohexylmethacrylate, cyclohexylacrylate, isobornyl (meth)acrylate, styrene, 4,6-trimethylstyrene (TMS), t-butyl styrene (TBS), trifluoroethyl (meth)acrylate, hexafluoro-isopropyl (meth)acrylate, hexafluorobutyl (meth)acrylate, or combinations thereof.
 78. The method of any one of embodiments 57 to 77, wherein the first and second lens-forming compositions comprise at least one polymerizable material selected from the group consisting of a UV-absorbing vinylic monomer, a UV/HEVL-absorbing vinylic monomer, a photochromic vinylic monomer, a polymerizable dye, and combinations thereof.
 79. The method of any one of embodiments 57 to 77, wherein the bulk hydrogel material is a silicone hydrogel material that has an equilibrium water content (i.e., in fully hydrated state or when being fully hydrated) of from about 20% to about 70% by weight, an oxygen permeability of at least about 40 barrers, and a modulus (i.e., Young's modulus) of from about 0.2 MPa to about 1.5 MPa.

The previous disclosure will enable one having ordinary skill in the art to practice the invention. Various modifications, variations, and combinations can be made to the various embodiment described herein. In order to better enable the reader to understand specific embodiments and the advantages thereof, reference to the following examples is suggested. It is intended that the specification and examples be considered as exemplary.

Example 1

Oxygen Permeability Measurements

Unless specified, the oxygen transmissibility (Dk/t), the intrinsic (or edge-corrected) oxygen permeability (Dk_i or Dk_c) of an insert and an insert material are determined according to procedures described in ISO 18369-4.

Equilibrium Water Content

The equilibrium water content (EWC) of contact lenses is determined as follows.

Amount of water (expressed as percent by weight) present in a hydrated hydrogel contact lens, which is fully equilibrated in saline solution, is determined at room temperature. Quickly stack the lenses, and transfer the lens stack to the aluminum pan on the analytical balance after blotting lens in a cloth. The number of lenses for each sample pan is typically five (5). Record the pan plus hydrated weight of the lenses. Cover the pan with aluminum foil. Place pans in a laboratory oven at $100 \pm 2^\circ\text{C}$ to dry for 16-18 hours. Remove pan plus lenses from the oven and cool in a desiccator for at least 30 minutes. Remove a single pan from the desiccator, and discard the aluminum foil. Weigh the pan plus dried lens sample on an analytical balance. Repeat for all pans. The wet and dry weight of the lens samples can be calculated by subtracting the weight of the empty weigh pan.

Elastic Modulus

The storage modulus (Young's modulus) of inserts is determined using a TA RSA-G2 DMA (Dynamic Mechanical Analyzer). The insert is cut into a 3.08 mm wide strip using Precision Concept dry lens cutter. Five thickness values are measured within 6.5mm gauge length. The strip is mounted on the instrument with metal grips. Oscillation temperature ramp test with a linear ramping rate at $2^\circ\text{C}/\text{minute}$ from $10^\circ\text{C} \sim 50^\circ\text{C}$ is applied on the insert, the material response to increasing temperature is monitored at a constant frequency of 1 Hz, constant amplitude of 0.5% deformation and sampling rate of 10.0 pts/s. Storage modulus (E'), loss modulus (E'') and $\tan \delta$ data are calculated by TRIOS software.

The elastic modulus of a silicone hydrogel material or contact lens is determined using a MTS insight instrument. The contact lens is first cut into a 3.12 mm wide strip using Precision Concept two stage cutter. Five thickness values are measured within 6.5mm gauge length. The strip is mounted on the instrument grips and submerged in PBS (phosphate buffered saline) with the temperature controlled at $21 \pm 2^\circ\text{C}$. Typically 5N Load cell is used for the test. Constant force and speed is applied to the sample until the sample breaks. Force and displacement data are collected by the TestWorks software. The elastic modulus value is calculated by the TestWorks software which is the slope or tangent of the stress vs. strain curve near zero elongation, in the elastic deformation region.

Delamination

Embedded hydrogel contact lenses are examined for possible delamination either using Optimec instrument or Optical Coherence Tomography (OCT).

Regardless of evaluation method, contact lenses are staged for a minimum of 12 hours at room temperature after autoclave run and prior to delamination study.

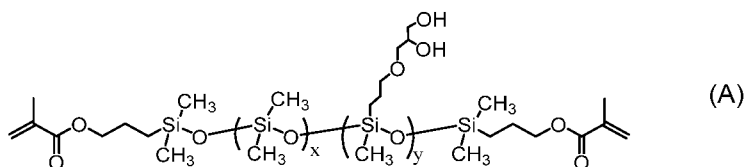
After meeting required staging time, fully hydrated contact lens is placed in a “V” graticule assembly of Optimec instrument (Model JCF; OPTIMEC England). After the contact lens is settled under the influence of gravity, the front view of the contact lens is inspected carefully for any sign of circular pattern. Delamination displays as circular patterns in Optimec image.

OCT (Spectral Domain Optical Coherence Tomography; Telesto-II; Thorlabs) could also be utilized to study delamination. OCT allows non-invasive imaging of the contact lens to obtain high resolution cross-section image. For this purpose, after meeting the minimum staging requirement, the contact lens is removed from its blister and is soaked into PBS solution for a minimum of 30 min to come to equilibrium. Then a cuvette with a “V” block feature will be filled approximately $\frac{3}{4}$ with fresh PBS solution and the contact lens will be transferred to the cuvette using Q-tips. The lens will be allowed to freely float to the “V” shape at the bottom of the cuvette and the entire contact lens will be scanned in increment of 10 degree. Delamination appears as air pocket in interval surface of insert and carrier in OCT images.

Chemicals

The following abbreviations are used in the following examples: PETA represents pentaerythritol tetraacrylate; TrisMA represents 3-[Tris(trimethylsiloxy)silyl]propyl methacrylate; HFIPMA represents hexafluoroisopropyl methacrylate; NPGDMA represents neopentyl glycol dimethacrylate; DMA represents N,N-dimethyl acrylamide; MMA represent methyl methacrylate; TEGDMA represent triethyleneglycol dimethacrylate; VAZO 67 represents 2,2'-azobis(2-methylbutyronitrile); EGBE represents ethylene glycol butyl ether; PBS represents a phosphate-buffered saline which has a pH of 7.2 ± 0.2 at 25°C and contains about 0.044 wt.% $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$, about 0.388 wt.% $\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$, and about 0.79 wt.% NaCl and; wt.% represents weight percent; PrOH represents 1-propanol; CE-PDMS represents a di-methacrylate-terminated chain-extended polydimethylsiloxane ($M_n \sim 9000$ g/mol), which has three polydimethylsiloxane (PDMS) segments linked via diurethane linkages between two PDMS segments and two urethane linkages each located between one terminal methacrylate group and one PDMS segment, is prepared according to method similar to what described in Example 2 of US8,529,057; “GA” macromer represents a di-methacryloyloxypropyl-terminated polysiloxane ($M_n \sim 6.8\text{K}$ g/mol, OH content ~ 1.2 meq/g) of formula (A) shown below; “H4” macromer represents a di-methacryloyloxypropyl-

terminated polysiloxane ($M_n \sim 11.3K-12.3K$ g/mol, OH content $\sim 1.82-2.01$ meq/g) of formula (A) shown below.



Example 3

Inserts

Rigid hydrophobic Inserts are prepared by thermal cast-molding of an insert-forming composition that comprises the following component: 39.3% by weight of HFIPMA; 18.34% by weight of NPGDMA; 38.8% by weight of TrisMA; 2.62% by weight of PETA; 0.44% by weight of Cu(II)-phthalocyanin particles dispersion; and 0.5% by weight of Perkadox-16.

An amount of the insert-forming composition is disposed in the center of the molding surface of a female insert mold half that is made of polypropylene. The female insert mold half with the insert-forming composition therein is closed with a male insert mold half which is made of polypropylene. The oven is configured as follows: a nitrogen supply is connected to the oven through a higher flow capacity controller which can control the flow rate of nitrogen through the oven; at the exhaust line of the oven, vacuum pumps are connected to control the differential pressure of the oven.

The insert-forming compositions in the insert molds are thermally cured in the oven under the following conditions: ramp from room temperature to 55°C at a ramp rate of about 7°C/minute; holding at 55°C for about 30-40 minutes; ramp from 55°C to 80°C at a ramp rate of about 7°C/minute; holding at 55°C for about 30-40 minutes; ramp from 80°C to 100°C at a ramp rate of about 7°C/minute; and holding at 100°C for about 30-40 minutes. The insert molds are opened and the molded inserts are removed from the insert-adhered mold halves.

The produced inserts have a diameter (from edge to edge of the insert) of about 5.0-8.0 mm, preferably around 6-7 mm.

Lens-Forming Compositions

Two lens-forming composition (i.e., SiHy lens formulation) are prepared at room temperature in air by blending all the components (materials) as shown in Table 1.

Table 1

Component	Lens-Forming Composition (Weight Unit Parts)	
	First	Second
GA	32	32
TrisMA	21	21
DMA	24	24
Irgacure 1173	1	1
PrOH	0	22
PPG (Mn~1KD)	18	0
2-Butoxy Ethanol	4	0
Viscosity (cP, 25°C)	31.6	13.5

The measurements of viscosity of a lens-forming composition is carried out as follows. About 0.5ml of a lens-forming composition prepared above is dosed into the Brookfield viscometer using the following spindle: CPA-40Z. All viscosity data are collected at 25°C. Lens-forming Composition I is measured at 5 rpm and Lens-forming Composition II is measured at 20 rpm.

Preparation of Embedded Silicone Hydrogel Contact Lenses

A drop (2 μ L) of the first lens-forming composition prepared above is dosed into a female lens mold half at center. An insert having a diameter of 8.0 mm prepared above is placed precisely on top of the drop of the first lens-forming composition in the center of the female lens mold half by using an insert precision placement tool (or anyone known to a person skilled in the art). An amount of the second lens-forming composition is introduced on to top of the insert in the female lens mold half to completely immerse the insert. A male lens mold half is placed on top of the female lens mold half, and then closed to form a molding assembly including the insert immersed in the second lens-forming composition. The first and second lens-forming compositions in the molding assembly are cured actinically by using a Mercury lamp-based UV box at an intensity of approximately 1-15 mW/cm² (preferably 2-10 mW/cm²) for 5-10 minutes to form an embedded hydrogel lens precursor. The molding assembly is opened and the molded embedded hydrogel lens precursor is removed from the lens molds.

Lens molds each with a molded silicone hydrogel lens precursor therein are mechanically opened. The molded embedded silicone hydrogel lens precursors adhere to the male lens mold halves or female lens mold halves. Molded embedded silicone hydrogel lens precursors adhered to male lens mold halves are delensed using ultrasonic unit; molded embedded silicone hydrogel lens precursors adhered to female lens mold halves are delensed manually from lens-adhered female lens mold halves with the aid of liquid nitrogen.

The delensed embedded silicone hydrogel lens precursors can be extracted with a mixture of 50:50 of propylene glycol:water. Preferably, the delensed embedded silicone hydrogel lens precursors are subjected to the following extraction/hydration, coating,

autoclave processes as follows. The embedded silicone hydrogel lens precursors are soaked in a bath containing deionized water or an aqueous solution of Tween 80 (500 PPM), for about 60 minutes, then in a bath containing an aqueous solution of polyacrylic acid (PAA, Mw 450K) at a concentration of ca. 0.1% by weight at 40°C for about 120 minutes; then in a bath containing a PBS solution at room temperature for about 60 minutes; packed/sealed in polypropylene lens packaging shells (or blisters) (one lens per shell) with 0.65 mL of an in-package-coating packaging saline which is prepared according to the procedure described in Example 19 of US8480227; and finally autoclaved for about 45 minutes at 121°C. The resultant embedded SiHy contact lenses each have a hydrogel coating thereon.

Figure 2 shows an image of a cross-section of the embedded SiHy contact lens comprising an insert embedded therein.

The obtained embedded SiHy contact lenses are examined for delamination according to the procedures described in Example 1. No bubble is observed under microscopy at interfaces between the insert and the SiHy bulk material within the embedded silicone hydrogel contact lens, i.e., no delamination.

All the publications, patents, and patent application publications, which have been cited herein above in this application, are hereby incorporated by reference in their entireties.

What is claimed is:

1. A method for producing embedded hydrogel contact lenses, comprising the steps of:
 - (1) obtaining a first lens-forming composition and a second lens-forming composition, wherein the first and second lens-forming compositions comprise identical polymerizable components (materials) but different non-reactive diluents, wherein the first lens-forming composition comprises a first non-reactive diluent and the second lens-forming composition comprises a second non-reactive diluent, wherein difference (ΔC_i) in the concentration of each polymerizable components (materials) between in the first lens-forming composition and in the second lens-forming composition is less than 10.0%, wherein $\Delta C_i = \frac{|C_{2i} - C_{1i}|}{C_{2i}} \times 100\%$ in which C_{1i} and C_{2i} are the concentrations of polymerizable component i in the first and second lens-forming compositions respectively, wherein ratio of the viscosity of the first lens-forming composition over the viscosity of the second lens-forming composition is at least 1.5;
 - (2) obtaining a lens mold, wherein the lens mold comprises a female lens mold half and a male lens mold half, wherein the female lens mold half has a first molding surface and a first central axis, wherein the male lens mold half has a second molding surface and a second central axis, wherein the first molding surface defines the anterior surface of an embedded hydrogel contact lens, wherein the second molding surface defines the posterior surface of the embedded hydrogel contact lens, wherein the female and male lens mold halves are configured to receive each other such that a mold cavity is formed between the first and second molding surfaces when the mold is closed;
 - (3) obtaining an insert which is made of a polymeric material and comprises a front surface, an opposite back surface, a third central axis, and a diameter up to about 13.0 mm;
 - (4) dosing from about 1 to about 20 μL of the first lens-forming composition in the center of the first molding surface of the female lens mold half;
 - (5) placing the insert on top of the first lens-forming composition on the first molding surface of the female lens mold half in a way to ensure that the third central axis coincides with the first central axis and the insert is held at a position above the first molding surface of the female lens mold half;
 - (6) placing the male lens mold half on top of the female lens mold half and closing the male and female lens mold halves to form a molding assembly comprising the first and second lens-forming compositions and the insert immersed therein in the molding assembly;

- (7) curing the first and second lens-forming compositions in the molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the first and second lens-forming compositions and the insert embedded in the bulk hydrogel material and centered in the embedded hydrogel lens precursor; (9) separating the lens mold obtained in step (8) into the male and female lens mold halves, with the embedded hydrogel lens precursor adhered on a lens-adhered lens mold half which is one of the male and female lens mold halves; (10) removing the embedded hydrogel lens precursor from the lens-adhered lens mold half (preferably before the embedded hydrogel lens precursor is contact with water or any liquid); and (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.
2. The method of claim 1, wherein the step of (8) curing the lens-forming composition is carried out actinically by using UV and/or visible light.
 3. The method of claim 1, wherein the step of (8) curing the lens-forming composition is carried out thermally by heating the first molding assembly in an oven at one or more curing temperatures selected from about 40°C to about 100°C.
 4. The method of any one of claims 1 to 3, wherein the first non-reactive diluent has a viscosity of greater than 20 cP at 20°C.
 5. The method of claim 4, wherein the first non-reactive diluent is a poly(C₂-C₄ alkyleneoxide) polymer, glycerol, propylene glycol, diethylene glycol, or mixtures thereof.
 6. The method of claim 4, wherein the first non-reactive diluent is a poly(ethyleneoxide) ("PEO"), poly(propyleneoxide) ("PPO"), poly(ethyleneoxide)-poly(propyleneoxide) di-block copolymer ("PEO-PPO"), poly(ethyleneoxide)-poly(propyleneoxide)-poly(ethyleneoxide) tri-block copolymer ("PEO-PPO-PEO"), poly(propyleneoxide)-poly(ethyleneoxide)-poly(propyleneoxide) tri-block copolymer ("PPO-PEO-PPO"), or mixtures thereof.
 7. The method of any one of claims 1 to 3, wherein the first non-reactive diluent has a viscosity of less than 5 cP at 20°C.
 8. The method of claim 7, wherein the first non-reactive diluent is dipropylene glycol methyl ether, ethylene glycol n-butyl ether, acetone, methyl ethyl ketone, diethylene glycol n-butyl ether, diethylene glycol methyl ether, propylene glycol methyl ether, propylene glycol methyl ether acetate, dipropylene glycol methyl ether acetate, propylene glycol n-propyl ether, dipropylene glycol n-propyl ether, tripropylene glycol n-

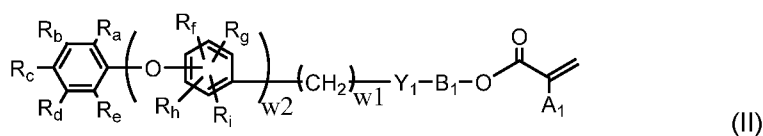
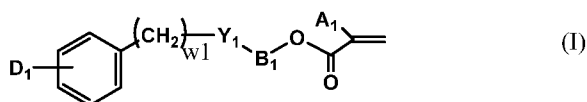
butyl ether, propylene glycol n-butyl ether, dipropylene glycol n-butyl ether, dipropylene glycol dimethyl ether, ethyl acetate, butyl acetate, amyl acetate, methyl lactate, ethyl lactate, i-propyl lactate, methylene chloride, 2-butanol, 1-propanol, 2-propanol, menthol, cyclohexanol, cyclopentanol, 2-pentanol, 3-pentanol, 2-hexanol, 3-hexanol, 3-methyl-2-butanol, tert-butanol, tert-amyl alcohol, 2-methyl-2-pentanol, 2,3-dimethyl-2-butanol, 3-methyl-3-pentanol, 1-methylcyclohexanol, 2-methyl-2-hexanol, 3-methyl-3-hexanol, 2,4-dimethyl-2-pentanol, 1-methylcyclopentanol, 1-ethylcyclopentanol, 1-ethylcyclopentanol, 1-ethoxy-2-propanol, 1-methyl-2-propanol, t-amyl alcohol, isopropanol, or mixtures thereof.

9. The method of any one of claims 1 to 8, wherein the polymeric material of the insert comprises: repeating units of at least one polymerizable photochromic compound, at least one UV-absorbing vinylic monomer, at least one UV/HEVL-absorbing vinylic monomer, at least one fluorescent vinylic monomer, or combinations thereof; at least one color-filtering material for correcting color blindness; a diffractive material; a high refractive-index material; or combinations.
10. The method of any one of claims 1 to 9, wherein the polymeric material of the insert is: a crosslinked polymethylmethacrylate; a crosslinked silicone polymer that has three-dimensional polymer networks, is insoluble in water, and has an equilibrium water content of about 5% or less by weight; a rigid gas permeable material; or a hydrophobic crosslinked acrylic material that has an equilibrium water content of less than 5% by weight and comprises at least 55% by mole of repeating units of one or more acrylic monomers and/or one or more acrylic crosslinker and at least about 6% by mole of repeating units of at least one acrylic crosslinking agent and optionally at least one vinylic crosslinking agent other than acrylic crosslinking agent.
11. The method of claim 10, wherein said at least one acrylic crosslinking agent is ethylene glycol dimethacrylate; ethylene glycol diacrylate; 1,3-propanediol diacrylate; 1,3-propanediol dimethacrylate; 2,3-propanediol diacrylate; 2,3-propanediol dimethacrylate; 1,4-butanediol dimethacrylate; 1,4-butanediol diacrylate; 1,5-pentanediol dimethacrylate; 1,5-pentanediol diacrylate; 1,6-hexanediol dimethacrylate; 1,6-hexanediol diacrylate; diethylene glycol dimethacrylate; diethylene glycol diacrylate; triethylene glycol dimethacrylate; triethylene glycol diacrylate; tetraethylene glycol dimethacrylate; tetraethylene glycol diacrylate; N,N'-methylene bis(acrylamide); N,N'-methylene bis(methacrylamide); N,N'-ethylene bis(acrylamide); N,N'-ethylene bis(methacrylamide); N,N'-hexamethylene bisacrylamide; N,N'-hexamethylene bismethacrylamide; pentaerythritol triacrylate, pentaerythritol trimethacrylate, trimethyloxypropane triacrylate, trimethyloxypropane trimethacrylate, tris(2-hydroxyethyl)isocyanurate triacrylate, tris(2-hydroxyethyl)isocyanurate trimethacrylate,

1,3,5-triacryloylhexahydro-1,3,5-triazine, 1,3,5-trimethacryloylhexahydro-1,3,5-triazine; pentaerythritol tetraacrylate, pentaerythritol tetramethacrylate, di(trimethyloxypropane) tetraacrylate, di(trimethyloxypropane) tetramethacrylate, or combinations thereof,

wherein said at least one vinylic crosslinking agent comprises divinylbenzene, 2-methyl-1,4-divinylbenzene, bis(4-vinylphenyl)methane, 1,2-bis(4-vinylphenyl)ethane, or combinations thereof.

12. The method of claim 10 or 11, wherein the polymeric material of the insert is the hydrophobic crosslinked acrylic material that comprises:
- repeating units of at least one silicone-containing acrylic monomer;
 - repeating units of at least one fluorine-containing acrylic monomer;
 - repeating units of at least one polysiloxane vinylic crosslinker;
 - repeating units of at least one aryl acrylic monomer of formula (I) or (II)



wherein A₁ is H or CH₃ (preferably H); B₁ is (CH₂)_{m1} or [O(CH₂)₂]_{z1} in which m₁ is 2-6 and z₁ is 1-10; Y₁ is a direct bond, O, S, or NR' in which R' is H, CH₃, C_nH_{2n+1} in which n'=1-10, iso-OC₃H₇, C₆H₅, or CH₂C₆H₅; R_a, R_b, R_c, R_d, R_e, R_f, R_g, R_h, and R_i independent of one another are H, C₁-C₁₂ alkyl, or C₁-C₁₂ alkoxy (preferably all are H); w₁ is 0-6, provided that m₁+w₁≤8; w₂ is an integer from 1 to 3; and D₁ is H, Cl, Br, C₁-C₄ alkyl, C₁-C₄ alkoxy, C₆H₅, or CH₂C₆H₅;

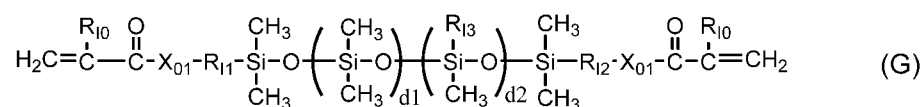
repeating units of at least one hydrophobic vinylic monomer selected from the group consisting of a vinyl alkanoate, a vinyloxyalkane, styrene, vinyl toluene, vinyl chloride, vinylidene chloride, 1-butene, and combinations thereof; or combinations thereof.

13. The method of any one of claims 1 to 12, wherein the first and second lens-forming compositions comprises at least 50% by mole of at least one hydroxyl-containing vinylic monomer selected from the group consisting of hydroxyethyl (meth)acrylate, glycerol (meth)acrylate, 3-hydroxypropyl (meth)acrylate, 2-hydroxypropyl (meth)acrylate, 3-amino-2-hydroxypropyl (meth)acrylate, N-2-hydroxyethyl (meth)acrylamide, N-3-hydroxypropyl (meth)acrylamide, N-2-hydroxypropyl (meth)acrylamide, N-2,3-dihydroxypropyl (meth)acrylamide, N-tris(hydroxymethyl)methyl (meth)acrylamide, vinyl alcohol, allyl alcohol, and

combinations thereof.

14. The method of any one of claims 1 to 13, wherein the first and second lens-forming compositions comprise (a) at least one polysiloxane vinylic monomer and/or at least one first polysiloxane vinylic crosslinker and (b) at least one hydrophilic vinylic monomer.
15. The method of claim 14, wherein the first and second lens-forming compositions comprise at least one hydrophilized polysiloxane vinylic crosslinker comprising hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one H-bond donor.
16. The method of 14 or 15, wherein said at least one hydrophilized polysiloxane vinylic crosslinker comprises:

(1) a vinylic crosslinker of formula (G)



in which:

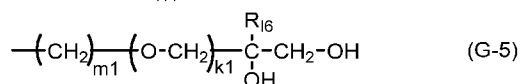
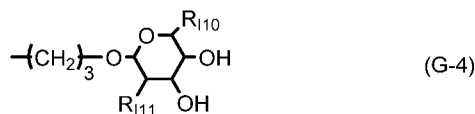
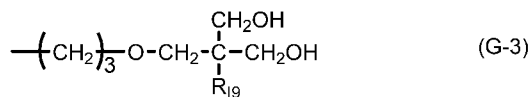
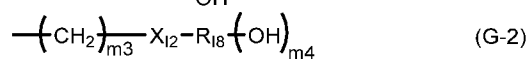
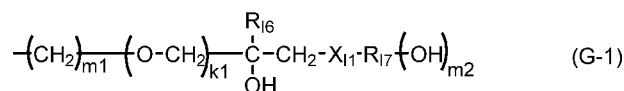
d1 is an integer of from 30 to 500 and d2 is an integer of from 1 to 75, provided that d2/d1 is from about 0.035 to about 0.15;

X₀₁ is O or NR_{IN} in which R_{IN} is hydrogen or C₁-C₁₀-alkyl;

R₁₀ is hydrogen or methyl;

R₁₁ and R₁₂ independently of each other are a substituted or unsubstituted C₁-C₁₀ alkylene divalent radical or a divalent radical of -R₁₄-O-R₁₅- in which R₁₄ and R₁₅ independently of each other are a substituted or unsubstituted C₁-C₁₀ alkylene divalent radical;

R₁₃ is a monovalent radical of any one of formula (G-1) to (G-5)



k1 is zero or 1; m1 is an integer of 2 to 4; m2 is an integer of 1 to 5; m3 is an integer of 3 to 6; m4 is an integer of 2 to 5;

R_{16} is hydrogen or methyl;

R_{17} is a C_2-C_6 hydrocarbon radical having (m_2+1) valencies;

R_{18} is a C_2-C_6 hydrocarbon radical having (m_4+1) valencies;

R_{19} is ethyl or hydroxymethyl;

R_{110} is methyl or hydromethyl;

R_{111} is hydroxyl or methoxy;

X_{11} is a sulfur linkage of $-S-$ or a tertiary amino linkage of $-NR_{112}-$ in which R_{112} is C_1-C_1 alkyl, hydroxyethyl, hydroxypropyl, or 2,3-dihydroxypropyl; and

X_{12} is an amide linkage of $-NR_{113}-\overset{\text{O}}{\overset{\parallel}{C}}-$ or $-\overset{\text{O}}{\overset{\parallel}{C}}-NR_{113}-$ in which R_{113} is hydrogen or C_1-C_{10} alkyl;

- (2) a vinylic crosslinker which comprises one sole polydiorganosiloxane segment and two terminal ethylenically-unsaturated groups selected from the group consisting of (meth)acryloyloxy groups, (meth)acryloylamino groups, vinyl carbonate groups, vinylcarbamate groups;
- (3) a chain-extended polysiloxane vinylic crosslinker which comprises at least two polydiorganosiloxane segment and a covalent linker between each pair of polydiorganosiloxane segments and two two terminal ethylenically-unsaturated groups selected from the group consisting of (meth)acryloyloxy groups, (meth)acryloylamino groups, vinyl carbonate groups, vinylcarbamate groups; or
- (4) combinations thereof.

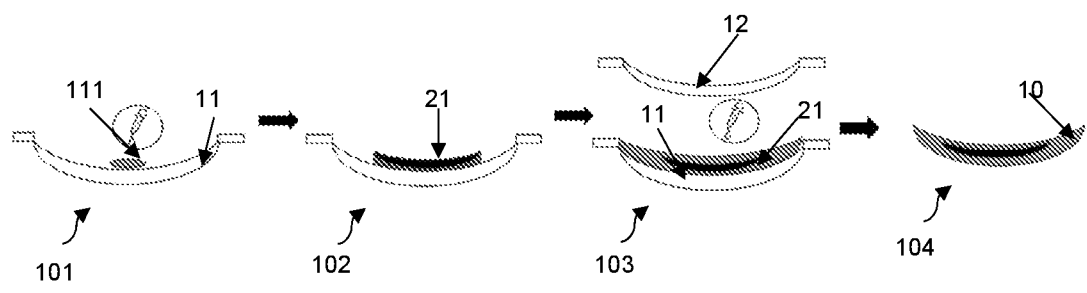


Figure 1

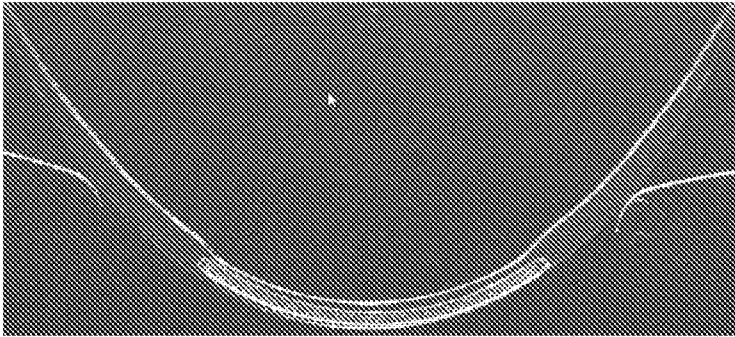


Figure 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2023/054760

A. CLASSIFICATION OF SUBJECT MATTER INV. B29D11/00 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) B29D		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2021/291469 A1 (ZHENG YANG [US] ET AL) 23 September 2021 (2021-09-23) abstract figure 4 paragraph [0319] claims 1-30	1-16
A	US 2014/268020 A1 (PUGH RANDALL B [US] ET AL) 18 September 2014 (2014-09-18) abstract figures 1-3	1-16
A	US 2017/312947 A1 (PUGH RANDALL BRAXTON [US] ET AL) 2 November 2017 (2017-11-02) abstract figures 1A-3	1-16
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☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
3 August 2023		11/08/2023
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Heckmann, Paul

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2023/054760

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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