ULTRA-HIGH DK MATERIAL

TECHNICAL FIELD

[0001] The present invention relates to ultra-high gas permeable (Dk) materials and methods of the same; and more particularly to ultra-high Dk materials having Dk values greater than 175; and still more particularly to ultra-high Dk suitable for use as rigid gas permeable contact lenses.

BACKGROUND OF THE INVENTION

[0002] Initially, rigid contact lenses were constructed of poly(methyl methacrylate) and were impermeable to oxygen. As a result, wearers of such lenses would quickly complain of eye fatigue and eye strain due to a lack of oxygen to the cornea. Thus, contact lens science advanced to silicone-based contact lenses, including rigid gas permeable (RGP) contact lenses. While RGP contact lenses do afford some degree of oxygen permeability (Dk values of 30-70, with some up to 140-145), wearers continue to cite eye fatigue and eye strain as the day progresses. While wear times have increased, fatigue and strain remain issues as a result of a lack of oxygen to the cornea. Thus, what is needed is a material suitable for use as a RGP lens which exhibits ultra-high oxygen permeability (Dk value greater than 175).

[0003] Oxygen for aerobic corneal metabolism is derived principally from the atmosphere. Therefore, the physiologic integrity of the cornea during wear of a gas-permeable soft or rigid contact lens is thought to be primarily dependent on the consumption of oxygen that passes through the lens. Prediction of the physiologic performance of a contact lens on the eye, therefore, requires an index that allows the oxygen passage through the lens to be estimated.

[0004] In 1971, Fatt and St. Helen applied Fick's Law to the problem of oxygen passage through contact lenses, thereby bringing to the field the concept of oxygen transmissibility (*Dk/t*). This bench-top measurement has been used extensively as a basis for comparison of contact lenses. However, as Fatt has pointed out, the *Dk/t* term used by itself as a measure of lens performance has been "a disappointment." The *Dk/t* coefficient gives a measure of the "ease" with which oxygen can diffuse through a lens; however, oxygen passage through a contact lens in a given scenario is also dependent on the driving force—that is, the partial pressure difference—across the lens. Oxygen flux (*j*) is the true index of the amount of oxygen that passes through a unit area of lens in a given time.

SUMMARY OF THE INVENTION

[0005] In accordance with an aspect of the present invention, a method of producing an ultra-high Dk material comprises contacting and reacting: a fluoroalkyl methacrylate; an alkyl glycol dimethacrylate; a hydrophilic agent, such as methacrylic acid; a hydroxyalkyl tris(trimethylsiloxy)silane; a hydroxyalkyl terminated polydimethylsiloxane; and styrylethyltris(trimethylsiloxy)silane. The reaction is conducted within an inert atmosphere at a pressure of at least 25 pounds per square inch (PSI) for a period of time and at a temperature sufficient to produce the ultra-high Dk material. By way of example, the fluoroalkly methacrylate may be hexafluoroisopropyl methacrylate; the alkyl glycol dimethacrylate may be neopentyl glycol dimethacrylate; the hydroxyalkyl tris(trimethylsiloxy)silane may be 3-methacryloyloxypropyl tris(trimethylsiloxy)silane; and the hydroxyalkyl terminated polydimethylsiloxane may be 4-methacryloxybutyl terminated polydimethylsiloxane. The

styrylethyltris(trimethylsiloxy)silane may comprise 14% of the material, by weight. The resultant material has a Dk value greater than 175.

[0006] In accordance with an aspect of the present invention, the reaction is conducted under a nitrogen, argon or helium atmosphere and is conducted between 25psi and 1,000psi (pounds per square inch). The reaction may be conducted within a thermostatically-controlled oven. Reaction temperate may be at room temperature (20°C-25°C) or at an elevated temperature, such as up to about 50°C. The oven may also be programmable to allow for variable temperature control over the course of the reaction. The reaction is further conducted within a vessel wherein the ultra-high Dk material is formed in the shape of the vessel. In one aspect, the high Dk material is formed as a blank or rod. The vessel may be constructed of a vessel material that is permeable to the inert gas comprising the inert atmosphere, such as polypropylene or polytetrafluoroethylene.

DETAILED DESCRIPTION

[0007] Polymerization of suitable monomeric reagents under high pressure may produce polymeric materials with an increase in oxygen permeability over reactions conducted at ambient pressure. When using starting monomers having high oxygen affinities, the increase in oxygen permeability may be even more pronounced. As a result, materials having ultra-high Dk values may be produced. As used herein, the term "ultra-high Dk" refers to materials having a Dk value greater than 175. To that end, polymerization reactions in accordance with the present invention are conducted under high pressure (at least 25psi) within a thermostatically-controlled oven at room temperature. "Room temperature" may be anywhere between 20°C and 25°C. In accordance with a further aspect of the present invention, the polymerization reactions may be

conducted at pressures higher than 25psi, including up to about 1000psi and/or higher temperatures, such as up to about 50°C. Higher oxygen permeabilities may be realized as the reaction pressure increases. Moreover, the polymerization reactions should be conducted in an inert atmosphere, such as, and without limitation thereto, a nitrogen, helium and/or argon atmosphere. Without being tied to any particular theory, it is believed that the ultra-high Dk polymer materials are formed as a xerogel or xerogel-like material. It is further believed that the inert gas acts like a solvent and once the polymer network is formed, the inert gas is replaced by ambient gases thereby forming a microporous structure. In a further aspect of the invention, the ultra-high Dk polymer materials may be produced under super critical fluid conditions. It is thus believe that the rigidity of the polymer network acquired through use of specific monomers and crosslinkers prevents collapse of the microporous structure.

[0008] In accordance with an aspect of the present invention, a non-limiting exemplary ultra-high Dk formulation is shown in Table 1:

TABLE 1

Component	Weight %	CAS Number
Hexafluoroisopropyl methacrylate	42.0	3063-94-3
Neopentyl glycol dimethacrylate	7.0	1985-51-9
Methacrylic acid	7.0	79-41-4
3-Methacryloyloxypropyl tris(trimethylsiloxy)silane	19.0	17096-07-0
4-methacryloxybutyl terminated polydimethylsiloxane	11.0	58130-03-3
styrylethyltris(trimethylsiloxy)silane	14.0	NA
TOTAL	100.0	

It should be noted that the weight percentage of styrylethyltris(trimethylsiloxy)silane (7% - 20%, and more particularly, 14%) combined with the polymerization under high pressure (at least 25psi) is critical to the production of the ultra-high Dk material. It is believed that the styrylethyltris(trimethylsiloxy)silane helps create a high free-volume structure and is synergistic with the 3-methacryloyloxypropyl tris(trimethylsiloxy)silane.

[0009] In accordance with a further aspect of the present invention, a method of producing an ultra-high Dk material comprises contacting and reacting: a fluoroalkyl methacrylate; an alkyl glycol dimethacrylate; a hydrophilic agent, such as methacrylic acid; a hydroxyalkyl tris(trimethylsiloxy)silane; a hydroxyalkyl terminated polydimethylsiloxane; and styrylethyltris(trimethylsiloxy)silane. By way of example and without limitation thereto, the fluoroalkly methacrylate may be hexafluoroisopropyl methacrylate; the alkyl glycol dimethacrylate may be neopentyl glycol dimethacrylate; the hydroxyalkyl tris(trimethylsiloxy)silane may be 3-methacryloyloxypropyl tris(trimethylsiloxy)silane; and the hydroxyalkyl terminated polydimethylsiloxane may be 4-methacryloxybutyl terminated polydimethylsiloxane. The reaction is conducted within an inert atmosphere (e.g., nitrogen, argon or helium) at a pressure of at least 25psi for a period of time and at a temperature sufficient to produce the ultra-high Dk material. As discussed above, the reaction may be conducted at room temperature, e.g., between about 20^{o}C and about 25^{o}C, or at an elevated temperature, such as up to about 50^{o}C, and under pressures between about 25psi and about 1,000psi. As a result, the ultra-high Dk material may have a Dk value greater than 175, with reactions conducted at higher pressures yielding materials with higher Dk values. Additionally, an ultra-high Dk material in accordance with the present invention may have relatively low silicon content, and thereby avoid surface wetting problems encountered with high silicon gas permeable materials.

As a result, the ultra-high Dk materials produced in accordance with the present invention do not require surface treatments, such as plasma treatments.

[0010] The polymerization reaction may be conducted within a vessel wherein the internal dimensions and geometry correspond to the desired size and shape of the ultra-high Dk material. That is, the ultra-high Dk material will polymerize within the vessel in the shape of the void of the vessel. The vessel may be constructed of a material, such as polypropylene or polytetrafluoroethylene (PTFE), that is permeable to the inert gas comprising the inert atmosphere. In accordance with an aspect of the invention, the vessel may reside with a thermostatically-controlled oven set at a specific temperature, such as between 20ºC and 50ºC, or the oven may be programmable so as to permit reactions with variable temperature profiles.

[0011] By way of example, an ultra-high Dk material produced in accordance with an aspect of the present invention may be used to fabricate rigid gas permeable (RGP) contact lenses. In this non-limiting example, the high Dk material may be formed as a lens, blank or rod having a diameter between about 7mm and 28mm. The blanks may have heights between about 2mm and about 15mm while the rods may have any desired heights. The diameter of the rod or blank may be selected in accordance with its intended use. For instance, traditional RGP contact lenses have diameters between about 7mm to about 12mm (typically between 9mm and 10mm) while scleral lenses have larger diameters between about 14mm to about 24mm (typically between 15mm and 20mm). The ultra-high Dk material blanks and rods may then be shaped through a lathing process to produce the desired lens, as is known in the art. Alternately, lenses may be cast directly under the described conditions.

[0012] Although the invention has been described with reference to preferred embodiments thereof, it is understood that various modifications may be made thereto without departing from the full spirit and scope of the invention as defined by the claims which follow.

CLAIMS

What Is Claimed Is:

1. A method of producing an ultra-high Dk material having a Dk value greater than 175, wherein the method comprises contacting and reacting:

a) a fluoroalkyl methacrylate;

b) an alkyl glycol dimethacrylate;

c) methacrylic acid;

d) a hydroxyalkyl tris(trimethylsiloxy)silane;

e) a hydroxyalkyl terminated polydimethylsiloxane; and

f) styrylethyltris(trimethylsiloxy)silane,

the reaction being conducted within an inert atmosphere at a pressure of at least 25 pounds per square inch (PSI) and for a period of time and at a temperature sufficient to produce the ultra-high Dk material, wherein the styrylethyltris(trimethylsiloxy)silane comprises between 7% and 20% of the material, by weight.

2. The method of claim 1 wherein the fluoroalkly methacrylate is hexafluoroisopropyl methacrylate; the alkyl glycol dimethacrylate is neopentyl glycol dimethacrylate; the hydroxyalkyl tris(trimethylsiloxy)silane is 3-methacryloyloxypropyl tris(trimethylsiloxy)silane; the hydroxyalkyl terminated polydimethylsiloxane is 4-methacryloxybutyl terminated polydimethylsiloxane.

3. The method of claim 2 wherein the styrylethyltris(trimethylsiloxy)silane comprises 14% of the material, by weight.

4. The method of claim 1 wherein the styrylethyltris(trimethylsiloxy)silane comprises 14% of the material, by weight.

5. The method of claim 1 wherein the material has a Dk value greater than 175.

6. The method of claim 1 wherein the reaction is conducted under a nitrogen, argon or helium atmosphere.

7. The method of claim 1 wherein the reaction is conducted between 25 psi and 1,000 psi.

8. The method of claim 1 wherein the reaction is conducted within a vessel wherein the ultra-high Dk material is formed in the shape of the vessel.

9. The method of claim 8 wherein vessel is selected whereby the high Dk material is formed as a lens, blank or rod.

10. The method of claim 8 wherein the vessel is constructed of a vessel material that is permeable to the inert gas comprising the inert atmosphere.

11. The method of claim 10 wherein the vessel is constructed of polypropylene or polytetrafluoroethylene.

12. The method of claim 1 wherein the reaction is conducted at room temperature.

13. The method of claim 1 wherein the reaction is conducted above room temperature.

14. An ultra-high Dk material produced according to the method of claim 1.