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(54) **POLYMER ADHESIVE FOR AN
INTRAOCULAR LENS THAT MINIMIZES
POSTERIOR CAPSULE OPACIFICATION**

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(57) **ABSTRACT**

Related U.S. Application Data

(62) Division of application No. 11/741,369, filed on Apr. 27, 2007, now Pat. No. 8,002,828.

(60) Provisional application No. 60/745,944, filed on Apr. 28, 2006.

Various polymers are provided that can be polymerized in the lens capsule with the ability to covalently bond an intraocular lens implant to the posterior capsule of the eye such that there is no space available between the intraocular lens implant and the lens capsule for lens epithelial cells to proliferate and thereby significantly reducing posterior capsule opacification.

POLYMER ADHESIVE FOR AN INTRAOCULAR LENS THAT MINIMIZES POSTERIOR CAPSULE OPACIFICATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of provisional application serial number 60/745,944 filed Apr. 28, 2006 and is related to U.S. application Ser. No. _____, entitled "Injectable Intraocular Lens that Minimizes Posterior Capsule Opacification and Methods and Materials for Realizing Same," filed concurrently herewith (Attorney Docket No. INN-019), both of which are herein incorporated by reference in their entireties.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention relates to artificial lens implants for the eye. 2. State of the Art

[0004] An intraocular lens (IOL) is an artificial lens implanted into the lens capsule of the eye in place of the natural crystalline lens of the eye because it has been clouded over by a cataract or injured. When the natural lens is removed from the lens capsule of the eye, lens epithelial cells (LECs) begin to multiply and spread on the posterior capsule and effectively render the posterior capsule opaque. This opacification, commonly referred to as posterior capsule opacification (PCO), causes clouding of vision and can lead to blurring and possibly total vision loss. While the LECs can theoretically spread on the anterior wall as well, due to the large opening in the anterior capsule (the capsulorrhexis), there is no wall for them to spread onto.

[0005] The occurrence of PCO is relatively high in traditional IOL implantations where the LECs spread between the IOL and the lens capsule. There have been some IOL designs where the sharpness of the corners of the lens has prevented cellular migration under the lens; however, recent literature suggests that these geometrical features simply retard the progression of PCO. PCO occurs in approximately 40% of IOL recipients within two years of receiving a synthetic lens.

[0006] The usual treatment for PCO is laser ablation of the posterior capsule where a laser is used to vaporize the posterior capsule and the cells that adhere to it. However, in terms of health economics, PCO is very expensive to treat. Therefore, it is desirable to avoid PCO at the outset.

SUMMARY OF THE INVENTION

[0007] The present invention describes various polymers that can be polymerized in the lens capsule with the ability to covalently bond an IOL to the posterior capsule of the eye such that there is no space available between the IOL implant and the lens capsule for the LECs to proliferate and thereby significantly reducing PCO.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0008] The invention consists of a polymeric adhesive synthesized in the lens capsule that reacts with or otherwise adheres to an IOL implant and also reacts with the nucleophiles of the posterior capsule. The polymer adhesive bonds the IOL implant to the posterior capsule, thereby eliminating space between the IOL implant and the posterior capsule where cells can migrate and thus significantly reducing PCO.

[0009] In one embodiment, a thin layer of polymeric adhesive material is spread over the posterior capsule. The IOL implant is placed in contact with the thin layer of polymeric adhesive material. The thin polymeric adhesive material reacts with or otherwise adheres to the IOL implant and reacts with the nucleophiles of the posterior capsule to effectively bond the IOL implant to the posterior capsule, thereby eliminating space between the IOL implant and the posterior capsule where cells can migrate. PCO is thereby significantly reduced.

[0010] In another embodiment, the polymeric adhesive material is encapsulated in one or more breakable microcapsules and placed on the IOL implant. Subsequent breakage of the microcapsule(s) dispenses the polymeric adhesive material onto the posterior capsule. The polymeric adhesive material is synthesized in the lens capsule and reacts with the IOL implant and with the nucleophiles of the posterior capsule to effectively bond the IOL implant to the posterior capsule, thereby eliminating space between the IOL implant and the posterior capsule where cells can migrate. PCO is thereby significantly reduced.

[0011] Examples of the nucleophiles that exist on the posterior capsule include hydroxyl groups, amine groups, acid groups, sulfur groups and the like. Polymers that have the ability to react with the nucleophiles of the posterior capsule to thereby bind the IOL implant to the posterior capsule include i) a prepolymer of polyisobutylene with isocyanate end groups, ii) polyurethanes and polyurethaneureas, iii) epoxides, iv) cyanoacrylates, v) proteinacious polymers, vi) carbohydrates or polysaccharides, and v) silicon rubber with reactive end groups as described below in more detail.

Prepolymer of Polyisobutylene With Isocyanate End Groups

[0012] In accordance with the present invention, a prepolymer of polyisobutylene with isocyanate end groups is provided. The prepolymer can be bifunctional and linear or multifunctional and starred. The isocyanate-terminated prepolymer can be loaded into the first barrel of a two barrel syringe. A reactive co-polymer is loaded into the second barrel of the two barrel syringe. An exemplary reactive co-polymer is a prepolymer of polyisobutylene with hydroxyl or amine end groups. The syringe is preferably realized from polypropylene and is free of air, moisture and any other nucleophile. The isocyanate-terminated prepolymer and the reactive co-polymer are preferably clear with a refractive index between 1.40 and 1.53. The streams from the two barrels of the syringe are merged in a static mixer located on the exit of the syringe. The mixture produced at the exit of the syringe, which is typically a viscous fluid, is injected through the capsulorrhexis such that it covers the posterior capsule. The IOL implant is positioned in the lens capsule in contact with the mixture. Other mechanisms (e.g., breakable microcapsules) can be used to locate the mixture between the posterior capsule and the IOL implant. Within the lens capsule, the isocyanate-terminated prepolymer will react with the reactive co-polymer to form a gel-type adhesive film. Simultaneous to this polymerization reaction, the reactive isocyanates of the prepolymer component chemically react with the nucleophiles (amine groups) of the posterior capsule, thereby forming a chemical bond between the gel-type adhesive film and the posterior capsule by formation of urea linkage. Such chemical bonding permanently adheres the IOL implant to the posterior capsule and eliminates spaces where lens epithelial cells can migrate and cause PCO. The reaction between the isocyanates of the prepolymer component and the nucleophiles (amine groups) of the posterior capsule does

not produce a byproduct that can otherwise be toxic to the eye. The resultant polymer of the gel-type adhesive film is preferably clear with a refractive index between 1.40 and 1.53.

[0013] Alternatively, the isocyanate-terminated prepolymer and the reactive co-polymer can be premixed prior to loading into a syringe and the contents injected through the capsulorrhexis such that it covers the posterior capsule. In this embodiment, slow reacting components must be used to enable flow through the syringe prior to polymerization.

Polyurethanes And Polyurethaneureas

[0014] Polyurethanes and polyurethaneureas are typically comprised of at least two components: an isocyanate-terminated prepolymer and a multinucleophilic co-polymer. An example of a polyurethane is the combination of a multiisocyanate such as the reaction product of a branched polytetramethylene macroglycol reacted with methylene bisphenyl diisocyanate (MDI) to provide a prepolymer that is isocyanate terminated. The multinucleophilic co-polymer can be the same macroglycol, such as polytetramethylene glycol that is terminated with hydroxyl groups. The hydroxyl groups of the multinucleophilic co-polymer react with the isocyanate groups of the multiisocyanate to produce a high molecular weight polyether urethane. This polyether urethane can be tailored to provide specific properties by adding chain extenders to the nucleophilic component of the polymer system, such as ethylene glycol and the like. Some polyurethanes are more stable than others in the body. U.S. Pat. No. 5,133,742, the details of which are herein incorporated by reference in its entirety, describes methods for increasing the biostability of these polymers.

[0015] In accordance with the present invention, a low molecular weight isocyanate-terminated prepolymer can be synthesized and loaded into the first barrel of a two barrel syringe. A hydroxyl-terminated co-polymer is loaded into the second barrel of the two barrel syringe. The streams from the two barrels of the syringe are merged in a static mixer (e.g., baffles) located on the exit of the syringe. The mixture produced at the exit of the syringe, which is typically a viscous fluid, is injected through the capsulorrhexis such that it covers the posterior capsule. The IOL implant is positioned in the lens capsule in contact with the mixture. Other mechanisms (e.g., breakable microcapsules) can be used to locate the mixture between the posterior capsule and the IOL implant. Within the lens capsule, the isocyanate-terminated prepolymer will react with the hydroxyl-terminated co-polymer to form a gel-type adhesive film. Simultaneous to this polymerization reaction, the reactive isocyanates of the prepolymer component chemically react with the nucleophiles of the posterior capsule, thereby forming a chemical bond between the gel-type adhesive film and the posterior capsule. Such chemical bonding permanently adheres the IOL implant to the posterior capsule and eliminates spaces where lens epithelial cells can migrate and cause PCO. The resulting gel-type adhesive film is preferably clear with a refractive index between 1.40 and 1.53.

[0016] Alternatively, the isocyanate-terminated prepolymer and the hydroxyl-terminated co-polymer can be premixed prior to loading into a syringe and the contents injected through the capsulorrhexis such that it covers the posterior capsule. In this embodiment, slow reacting components must be used to enable flow through the syringe prior to polymerization.

[0017] An exemplary hydroxyl-terminated co-polymer that can be used in this capacity is a polyisobutylene (PIB) diol as it will provide a rubbery polyurethane-based gel that is biostable. Other hydroxyl-terminated co-polymers are per-

fluoropolyethyleneglycol polytetramethyleneglycol, poly(hexamethylene carbonate)diol, and the like. Preferably the macroglycol is biostable and has an index of refraction between 1.40 and 1.53.

Epoxies

[0018] Epoxies function in a manner similar to polyurethanes but include an epoxide-terminated prepolymer (rather than the isocyanate-terminated prepolymer) and a multinucleophilic co-polymer. The epoxide-terminated prepolymer and the multinucleophilic co-polymer are mixed and the resulting mixture is injected through the capsulorrhexis such that it covers the posterior capsule. The IOL implant is positioned in the lens capsule in contact with the mixture. Other mechanism can be used to locate the mixture between the posterior capsule and the IOL implant. Within the lens capsule, the epoxide-terminated prepolymer will react with the multinucleophilic co-polymer to form a gel-type adhesive film. Simultaneous to this polymerization reaction, the reactive epoxide groups of the prepolymer component chemically react with the nucleophiles of the posterior capsule, thereby forming a chemical bond between the gel-type adhesive film and the posterior capsule. Such chemical bonding permanently adheres the IOL implant to the posterior capsule and eliminates spaces where lens epithelial cells can migrate and cause PCO. The resulting gel-type adhesive film is preferably clear with a refractive index between 1.40 and 1.53.

[0019] Alternatively, the epoxide-terminated prepolymer and the multinucleophilic co-polymer epoxy can be premixed prior to loading into a syringe and the contents injected through the capsulorrhexis such that it covers the posterior capsule. In this embodiment, a slow reacting epoxy, such as the 5 minute epoxies, must be used to enable flow through the syringe prior to polymerization.

[0020] Suitable epoxies include glycidyl-terminated polytetramethylene glycol, glycidyl-terminated polyisobutylene, glycidyl terminated perfluoroethyleneoxide, and the like.

Cyanoacrylates (CA)

[0021] In accordance with the invention, a polymeric material with cyanoacrylate end groups is provided that readily transforms to a soft rubbery gel (e.g., shore A=20) in the lens capsule upon contact with moisture and/or proteins within the lens capsule to form a gel-type adhesive film. Simultaneous to this polymerization reaction, the reactive cyanoacrylate groups chemically react with the nucleophiles of the posterior capsule, thereby forming a chemical bond between the gel-type adhesive film and the posterior capsule. Such chemical bonding permanently adheres an IOL implant to the posterior capsule and eliminates spaces where lens epithelial cells can migrate and cause PCO. The cyanoacrylate-terminated polymer as well as the resulting gel-type adhesive film are preferably clear with a refractive index between 1.40 and 1.53.

[0022] Suitable cyanoacrylate (CA) terminated materials that yield soft rubber-like gels upon contact with moisture and/or proteins within the lens capsule include:

[0023] i) 3-arm star cyanoacrylate (CA)-telechelic PIB [\emptyset (PIB-CA)₃];

[0024] ii) CA-PDMS-CA where PDMS is poly(dimethyl siloxane);

[0025] iii) CA-PEG-CA where PEG is polyethylene glycol; and

[0026] iv) CA-PEG-b-PDMS-b-PEG-CA.

A liquid form cyanoacrylate-based material (such as liquid CA-PDMS-CA) can be used as such (in bulk). Preferably, it is loaded into a syringe and injected into the lens capsule from the syringe. Alternatively, a non-fluid form cyanoacrylate-based material (such as crystalline PEG-based material) is preferably dissolved in a suitable solvent (such as DMSO, a non-protic, biocompatible FDA approved solvent) to render the prepolymer injectable. The cyanoacrylation method seems to be of general applicability and can be used for the cyanoacrylation of a great variety of hydroxide-containing molecules.

[0027] Aromatic silicone cyanoacrylates can also be used which have a higher refractive index. A PIB-based cyanoacrylate material can also be used. Such material has an even higher refractive index.

[0028] A table of other potential cyanoacrylate-based materials follows below. An initiator component (e.g., N,N-dimethyl-p-toluidine in n-C₆H₁₄) can also be mixed with a cyanoacrylate-based material to ensure completeness of the reaction that forms the gel-type intraocular lens. The Fn number in the chart below represents the functionality number of the polymer material and relates to the number of end groups per mole of the polymer material.

Polymers	Visual appearance	MW (g/mol)	F _n ^a	Initiator	Remarks	Swelling test	Softness
CA-PIB-CA CA	light brown, highly viscous not, injectable by syringe	4000	2.5	N,N-dimethyl-p-toluidine in n-C ₆ H ₁₄	crosslinks upon contact with initiator sol fraction 15% in THF	108% in hexanes	too soft to measure even by Shore A
				egg yolk	crosslinks (hard to separate egg yolk and polymer)		
CA-PIB-CA CA	light brown, low viscosity liquid, flows freely, injectable by syringe	1330	2.9	N,N-dimethyl-p-toluidine in n-C ₆ H ₁₄	crosslinks during storage within 2-3 days, sol fraction 5% in THF	37% in hexanes	Shore A = 40
				glass surface (moisture)	crosslinks during storage within 2-3 days		
CA-PDMS-CA	light brown, low viscosity liquid, flows freely, injectable by syringe	5000	1.9	N,N-dimethyl-p-toluidine in n-C ₆ H ₁₄	crosslinks during storage within 2-3 days, sol fraction 10% in THF	360% in hexanes	too soft to measure even by Shore A
				egg yolk glass surface (moisture)	crosslinks (hard to separate egg yolk and polymer) crosslinks during storage within 2-3 days, sticks to glassware		
CA-PEG-CA	brown solid	2000	1.9	glass surface (moisture)	soluble in DMSO, solution syringible, crosslinks upon contact with moisture, crosslinks during storage in less than 1 hr., becomes rubbery upon DMSO addition, solubility limit in DMSO: 50 wt. %	1010% (in water) 612% (in DMSO)	too soft to measure even by Shore A
CA-PEG-PDMS-PEG-CA	light brown, low viscosity liquid, flows freely, injectable by syringe	4000 (PDMS = 40%)	0.8	N,N-dimethyl-p-toluidine in THF	crosslinks experiment to be repeated with F _n ~2.0 triblock		THF extracted product: too soft to measure even by Shore A

[0029] In an exemplary embodiment, the CA-terminated material is applied as a thin layer to the posterior capsule. The IOL implant is placed in contact with the thin CA-terminated material. Upon contact with moisture and/or proteins within the lens capsule, the CA-terminated material undergoes a polymerization reaction that forms a gel-type adhesive film. Simultaneous to the polymerization reaction, the CA-terminated material reacts with the IOL implant and reacts with the nucleophiles of the posterior capsule to effectively bond the IOL implant to the posterior capsule, thereby eliminating space between the IOL implant and the posterior capsule where cells can migrate and thus significantly reducing PCO.

[0030] In another embodiment, the CA-based material is encapsulated in one or more breakable microcapsules and placed on the IOL implant and/or on the posterior capsule. The IOL implant is placed such that microcapsules are disposed between the IOL implant and the posterior capsule. Subsequent breakage of the microcapsule(s) dispenses the polymeric adhesive material onto the posterior capsule. The polymeric adhesive material is synthesized in the lens capsule. The polymeric adhesive material reacts with the IOL implant and reacts with the nucleophiles of the posterior capsule to effectively bond the IOL implant to the posterior capsule, thereby eliminating space between the IOL implant and the posterior capsule where cells can migrate and thus significantly reducing PCO.

Proteinacious Polymers And Carbohydrates Or Polysaccharides

[0031] Proteinacious polymers can also be used in this invention. Here, slurries of collagen, elastin, and/or other peptides can be mixed with one or more cross-linking agents (such as formaldehyde, glutaraldehyde, carbodiimide and the like) and applied as a thin layer to the posterior capsule. The IOL implant is placed in contact with this thin layer. Other mechanisms (e.g., breakable microcapsules) can be used to locate the mixture between the posterior capsule and the IOL implant. Within the lens capsule, the cross-linking agent reacts with the proteinacious polymer to form a gel-type adhesive film. Simultaneous to this cross-linking reaction, the cross-linking agent chemically reacts with the nucleophiles of the posterior capsule, thereby forming a chemical bond between the gel-type adhesive film and the posterior capsule. Such chemical bonding effectively bonds the IOL implant to the posterior capsule and eliminates spaces where lens epithelial cells can migrate and cause PCO. The proteinacious polymer and the cross-linking agent(s) as well as the resulting gel-type adhesive film are preferably clear with a refractive index between 1.40 and 1.53.

[0032] Similarly, carbohydrate or polysaccharide gel-like materials can be used for this purpose. Such gel like materials can include alginate, pectin, carrageenan, gellan, starch and the like. The gel like materials are mixed with one or more cross-linking agents (such as multivalent cations including calcium chloride, barium chloride and the like; more permanent cross-linking agents can also be used including the epoxides and the multiisocyanates as described above). This mixture is applied as a thin layer to the posterior capsule. The IOL implant is placed in contact with this thin layer. Other mechanisms (e.g., breakable microcapsules) can be used to locate the mixture between the posterior capsule and the IOL implant. Within the lens capsule, the cross-linking agent reacts with the gel-like material to form a gel-type adhesive film. Simultaneous to this cross-linking reaction, the cross-linking agent chemically reacts with the nucleophiles of the

posterior capsule, thereby forming a chemical bond between the gel-type adhesive film and the posterior capsule. Such chemical bonding effectively bonds the IOL implant to the posterior capsule and eliminates spaces where lens epithelial cells can migrate and cause PCO. The carbohydrate or polysaccharide gel-like materials and the cross-linking agent(s) as well as the resulting gel-type adhesive film are preferably clear with a refractive index between 1.40 and 1.53.

Silicone Rubber With Reactive End Groups

[0033] Prepolymers of silicone rubber can be made with reactive end groups (e.g., methoxy, ethoxy, acetoxy, hydrogen, chlorine and others) that can both initiate polymerization and react with tissue at the same time to effectively gel and bond the IOL implant to the posterior capsule. It is important that the reactive end group be non-toxic to the posterior capsule.

[0034] In an exemplary embodiment, the silicon-based material is applied as a thin layer to the posterior capsule. The IOL implant is placed in contact with the thin silicon-based adhesive layer. Simultaneous to the polymerization reaction, the adhesive layer reacts with the IOL implant and with the nucleophiles of the posterior capsule reactive to effectively bond the IOL implant to the posterior capsule, thereby eliminating space between the IOL implant and the posterior capsule where cells can migrate and thus significantly reducing PCO.

[0035] In another embodiment, the silicon-based material is encapsulated in one or more breakable microcapsules and placed on the IOL implant and/or on the posterior capsule. The IOL implant is placed such that microcapsules are disposed between the IOL implant and the posterior capsule. Subsequent breakage of the microcapsule(s) dispenses the polymeric adhesive material onto the posterior capsule. The polymeric adhesive material is synthesized in the lens capsule, and also reacts with the IOL implant and reacts with the nucleophiles of the posterior capsule to effectively bond the IOL implant to the posterior capsule, thereby eliminating spaces between the IOL implant and the posterior capsule where cells can migrate and thus significantly reducing PCO.

[0036] Although the polymeric adhesive material described herein employs a polymerization reaction to the nucleophiles (e.g., hydroxyl groups) of the posterior capsule to effectively bind thereto, this polymerization reaction can be initiated and continued with small amounts of water.

Use of A Tacky Polymer

[0037] In another embodiment, a tacky adhesive is placed on the IOL and the lens is pressed against the lens capsule. Here there is no physical bond between the lens and the IOL, rather they are coupled by hydrophobic interactions.

[0038] There are certain polymers that are both tacky and hydrophobic in nature and can be used to adhere an IOL to the lens capsule. Exemplary polymers include polybutadiene, polyisoprene or polyisobutylene polymers of molecular weight less than 100,000 Daltons; preferably between 500 and 30,000 Daltons. These polymers can be syringed onto the posterior or anterior walls of the lens capsule and an IOL pressed against it to effectively bond the IOL to the wall of the lens capsule. Although these bonds are non-reactive, the hydrophobic and tacky nature of the polymer will hold the IOL in place and provide a boundary which will prevent cells from migrating between the IOL and the lens capsule.

[0039] In another embodiment of the invention, an IOL can be bonded to the posterior wall of the lens capsule or the anterior wall of the lens capsule or alternatively, two IOLs can be used where one is attached to the posterior capsule and another to the anterior capsule. In this manner, the lenses are able to move closer or further apart from each other depending upon the pressure in the vitreous humour or upon the tension exerted on the lens capsule by the zonules. In this manner, the lenses behave like a telescope and will allow focusing of an image on the retina. In this manner, the eye is capable of accommodating. The adhesive provides both a means of supporting the IOLs as well as preventing epithelial cells from spreading between the lens capsule and the IOL.

[0040] There have been described and illustrated herein several embodiments of a polymeric adhesive material for bonding an intraocular lens implant to the posterior capsule of the eye in a manner that minimizes posterior or anterior capsule opacification. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise. It will therefore be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as claimed herein.

1-9. (canceled)

10. A method comprising:

inserting an intraocular lens implant into the lens capsule of the eye; and

interposing a polymeric adhesive material between the intraocular lens implant and a capsular wall, said polymeric adhesive material reacting with the intraocular lens and reacting with nucleophiles of the capsular wall to bond the intraocular lens implant to the capsular wall in a manner that reduces space between the intraocular lens implant and the capsular wall;

wherein said polymeric adhesive material comprises a silicone rubber with reactive end groups selected from the group including i) methoxy groups, ii) ethoxy groups, iii) acetoxy groups, iv) hydrogen groups, v) chlorine groups, and vi) any combination of the above.

11-17. (canceled)

18. A method according to claim 10, wherein:

said polymeric adhesive material reactively polymerizes within the lens capsule of the eye.

19. A method according to claim 10, wherein:

said polymeric adhesive material is applied as a thin layer to the capsular wall.

20. A method according to claim 10, wherein:

said polymeric adhesive material is encapsulated in one or more breakable microcapsules that are interposed between the intraocular lens implant and the capsular wall and then broken to dispense the polymeric adhesive material therebetween.

21. A method according to claim 10, wherein:

said capsular wall comprises a posterior capsule wall.

22. A method according to claim 10, wherein:

said intraocular lens implant is an accommodating intraocular lens implant.

23. A method according to claim 22, wherein:

said intraocular lens implant includes first and second intraocular lens implant, wherein the first intraocular lens is bonded to an anterior capsule wall by the polymeric adhesive material in a manner that reduces space between the first intraocular lens implant and the anterior capsule wall, and wherein the second intraocular lens is bonded to a posterior capsule wall by the polymeric adhesive material in a manner that reduces space between the intraocular lens implant and the posterior capsule wall.

24-25. (canceled)

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