compound is effectively cross-linked; the collagen is only slightly cross-linked by gamma irradiation of 1.0Mrd total dose.

United States Patent No. 4,452,929 describes an aqueous coating composition with a collagen concentration of about 1.5% in the final collagen-ethylenically unsaturated compound hydrogel.

Examples of vision enhancing ophthalmic materials that are non-biodegradable and allow regeneration of corneal cells and nerves when implanted have been reported. However, despite these properties, these materials still lack the elasticity and optimum toughness for easy handling during surgery, especially under sub-optimal conditions such as in developing countries.

Accordingly, there remains a need for materials that can be used in ophthalmic devices and that have the required elasticity and toughness for handling during surgery.

This background information is provided for the purpose of making known information believed by the applicant to be of possible relevance to the present invention. No admission is necessarily intended, nor should be construed, that any of the preceding information constitutes prior art against the present invention.

SUMMARY OF THE INVENTION

~~An object~~ One aspect of the present invention is to provide interpenetrating polymeric networks (IPNs), and related methods and compositions.

In accordance with ~~one~~ a particular aspect of the present invention, there is provided a hydrogel material comprising an interpenetrating network of two or more polymer networks, wherein at least one of the polymer networks is based on a biopolymer.

In accordance with another aspect of the present invention, there is provided a method of producing a hydrogel material according to the present invention, the method comprising, combining a first polymeric network with a second polymeric network, wherein the first polymeric network or the second polymeric network is based on a biopolymer.

In accordance with another aspect of the invention, there is provided a kit for producing a hydrogel material according to the present invention, the kit comprising, (i) an

The invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word “comprise”, and variations such as “comprises” and “comprising”, will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

~~CLAIMS~~

1. ~~A hydrogel material comprising an interpenetrating network of two or more polymer networks, wherein at least one of the polymer networks is based on a biopolymer.~~

2. ~~The hydrogel material according to claim 1, wherein the biopolymer is, denatured gelatin, fibrin-fibrinogen, elastin, glycoprotein, polysaccharide, glycosaminoglycan, proteoglycan, or oxidized polysaccharide or any combination thereof.~~

3. ~~The hydrogel material according to claim 2, wherein the collagen is Type I collagen, Type II collagen, Type III collagen, Type IV collagen, Type collagen V, Type VI collagen, denatured collagen or recombinant collagen.~~

4. ~~The hydrogel material according to claim 2, wherein the polysaccharide is alginate, chitosan, N-carboxymethyl chitosan, O-carboxymethyl chitosan, N,O-carboxymethyl chitosan, hyaluronic acid or chondroitin sulphates.~~

5. ~~The hydrogel material according to claim 2, wherein the oxidized polysaccharide is oxidized chondroitin sulphate, oxidized alginate or oxidized hyaluronic acid.~~

6. ~~The hydrogel material according to claim 1, wherein at least one of the polymer networks is based on a synthetic polymer.~~

7. ~~The hydrogel according to claim 6, wherein the synthetic polymer is alkyl acrylamide, water soluble polyethylene glycol diacrylate, acrylic acid and its derivatives, alkyl acylate, methylacrylic acid and its derrivatives, alkyl methacrylate, 2-hydroxyethyl methacrylate, 2-methacryloyloxyethyl phosphorylcholine, vinyl pyrrolidone or glycomonomer.~~

8. ~~The hydrogel material according to any one of claims 1 to 7, wherein the material is characterized by at least one of low cytotoxicity, no cytotoxicity, an ability to facilitate cell and/or nerve growth, moldability, an ability to withstand handling, implantation, suturing and/or post-installation wear and tear.~~

9. ~~The hydrogel material according to any one of claims 1 to 8 additionally comprising a bioactive agent or a drug.~~

10. The hydrogel material according to any one of claims 1 to 8, for use as an ophthalmic onlay or implant.

11. The hydrogel material according to any one of claims 1 to 8 for use in drug delivery.

12. A method of producing a hydrogel material according to any one of claims 1 to 10, the method comprising, combining a first polymer network with a second polymer network, wherein at least one of the first polymer network and the second polymer network is based on a biopolymer and maintains the resultant reaction mixture under conditions suitable for formation of an interpenetrating network.

13. The method according to claim 10, wherein said first and second polymer networks are combined with at least one cross-linking agent.

14. The method according to claim 12 or 13, wherein the reaction mixture is maintained at an acidic pH.

15. The method according to any one of claims 12 to 14, wherein the reaction mixture is placed in a mold and allowed to cure.

16. A device comprising the hydrogel material according to any one of claims 1 to 11, which device is suitable for administration to a mammal.

17. The device according to claim 16, which is an ophthalmic device.

18. The device according to claim 16 or 17, wherein said device comprises a bioactive agent or a drug for delivery to said mammal.

19. The device according to claim 18, wherein said bioactive agent or drug is dispersed within the hydrogel.

20. The device according to claim 18, wherein the drug is contained within nano- or microspheres dispersed within the hydrogel material.

21. The device according to claim 19, wherein the bioactive agent is a growth factor, retinoid, enzyme, cell adhesion factor, extracellular matrix glycoprotein, hormone, osteogenic factor, cytokine, antibody, antigen, biologically active protein, pharmaceutical compound, peptide, fragments or motifs derived from biologically active protein, anti-bacterial agent or anti-viral agents.

CLAIMS

1. An implantable, optically clear, ophthalmic device, wherein the device is a corneal onlay, corneal inlay, or full-thickness corneal implant, and comprises an interpenetrating network of two or more polymer networks, wherein:

a monomer that, after being mixed with a previously formed biopolymer that can be cross-linked to form a hydrogel, is polymerized to form a second polymer entangled with the previously formed biopolymer,

wherein the second polymer is then crosslinked to form a first network, and

wherein the previously formed biopolymer is then crosslinked to form a second network entangled with the first network, thereby forming a hydrogel interpenetrating network.

2. The device according to claim 1, wherein the biopolymer is, denatured gelatin, fibrin-fibrinogen, elastin, glycoprotein, polysaccharide, glycosaminoglycan, proteoglycan, or oxidized polysaccharide or any combination thereof.

3. The device according to claim 2, wherein the biopolymer is Type I collagen, Type II collagen, Type III collagen, Type IV collagen, Type V collagen, Type VI collagen, denatured collagen or recombinant collagen.

4. The device according to claim 2, wherein the polysaccharide is alginate, chitosan, N-carboxymethyl chitosan, O-carboxymethyl chitosan, N,O-carboxymethyl chitosan, hyaluronic acid or chondroitin sulphates.

5. The device according to claim 2, wherein the oxidized polysaccharide is oxidized chondroitin sulphate, oxidized alginate or oxidized hyaluronic acid.

6. The device according to claim 1, wherein the second network is formed from either a synthetic polymer or a second biopolymer.

7. The device according to claim 6, wherein the synthetic polymer is alkyl acrylamide, water soluble polyethylene glycol diacrylate, acrylic acid or its derivatives, alkyl acrylate, methylacrylic acid or its derivatives, alkyl methacrylate, 2-hydroxyethyl methacrylate, 2-methacryloyloxyethyl phosphorylcholine, vinyl pyrrolidone or glycomonomer.

8. The device according to any one of claims 1 to 7, wherein the device is characterized by low cytotoxicity or no cytotoxicity, and after molding the hydrogel interpenetrating network, the device has an ability to facilitate cell and/or nerve growth and to withstand handling, implantation, suturing and/or post-installation wear and tear.

9. The device according to any one of claims 1 to 8 additionally comprising a bioactive agent or a drug.

10. The device according to any one of claims 1 to 9, wherein the device is a corneal onlay and wherein the device is effective in facilitating re-epithelialization over the anterior surface of the device.

11. The device according to any one of claims 1 to 10 for use in drug delivery.

12. A method of producing an implantable, optically clear, ophthalmic device, the method comprising:

providing a first biopolymer that can be cross-linked to form a hydrogel,

mixing a monomer with the first biopolymer,

polymerizing the monomer to form a second polymer entangled with the first biopolymer,

crosslinking the second polymer to form a first network,

crosslinking the first biopolymer to form a second network, thereby forming a hydrogel interpenetrating network, and

molding the hydrogel interpenetrating network.

13. The method according to claim 12, wherein cross-linking is performed at acidic pH.

14. The method according to claim 12 or 13, wherein cross-linking is performed at a pH of 5.

15. The method according to any one of claims 12 to 14, wherein the hydrogel interpenetrating network is molded to form a corneal onlay, corneal inlay, or full-thickness corneal implant.

16. A device comprising the hydrogel material according to any one of claims 1 to 11, which device is suitable for administration to a mammal.

17. The device according to claim 16, which is implanted on or in the cornea of a mammal.

18. The device according to claim 16 or 17, wherein said device comprises a bioactive agent or a drug for delivery to said mammal.

19. The device according to claim 18, wherein said bioactive agent or drug is dispersed within the hydrogel.

20. The device according to claim 18, wherein the drug is contained within nano- or microspheres dispersed within the hydrogel material.

21. The device according to claim 19, wherein the bioactive agent is a growth factor, retinoid, enzyme, cell adhesion factor, extracellular matrix glycoprotein, hormone, osteogenic factor, cytokine, antibody, antigen, biologically active protein, pharmaceutical compound, peptide, fragment or motif derived from biologically active protein, anti-bacterial agent or anti-viral agent.

22. The device according to claim 1, wherein said interpenetrating network comprises at least 40% by weight biopolymer out of total polymer weight and maintains its form at physiological temperature.

23. An implantable, optically clear, ophthalmic device of uniform refractive index, wherein the device is a corneal onlay, corneal inlay, or full-thickness corneal implant, and comprises an interpenetrating network of two or more polymer networks, wherein said interpenetrating network comprises:

a monomer that, after being mixed with a collagen or chitosan biopolymer, is polymerized to form a second polymer entangled with the collagen or chitosan biopolymer,

wherein the second polymer is then crosslinked to form a first network, and

the collagen or chitosan biopolymer is then crosslinked to form a second network entangled with the first network, thereby forming a hydrogel interpenetrating network, and molded into a corneal onlay, inlay, or implant.