suitable for placement in the anterior chamber or vitreous body of an eye to thereby form an intraocular implant, wherein the prostamide comprises about 20% of the implant by weight, the ester end poly(D,L-lactide) comprises about 20% of the implant by weight, the acid end poly(D,L-lactide) comprises about 15% of the implant by weight, the ester end poly(D,L-lactide-co-glycolide) comprises about 40% of the implant by weight, and the polyethylene glycol 3350 comprises about 5% of the implant by weight.

[00054] A further embodiment is an intraocular biodegradable implant made by any of the methods described above.

[00055] Unless otherwise specified the inherent viscosity for the PLA and PLGA polymers set forth herein is measured for a 0.1% solution of the polymer in chloroform at 25°C.

[00055a] Another embodiment of the present invention is a biodegradable intraocular implant for reducing intraocular pressure (IOP) in an eye, the implant comprising a biodegradable polymer matrix, polyethylene glycol 3350, and a prostamide as the active agent, wherein the prostamide and polyethylene glycol 3350 are associated with the biodegradable polymer matrix, which comprises

a) an ester end poly(D,L-lactide) having an inherent viscosity of 0.25-0.35 dl/g,
b) an acid end poly(D,L-lactide) having an inherent viscosity of 0.16-0.24 dl/g, and
c) an ester end poly(D,L-lactide-co-glycolide) having an inherent viscosity of 0.16-0.24 dl/g and a D,L-lactide to glycolide molar ratio of about 75:25;

wherein the prostamide constitutes 18 to 22% of the implant by weight, the ester end poly(D,L-lactide) constitutes 18 to 22% of the implant by weight, the acid end poly(D,L-lactide) constitutes 13.5 to 16.5% of the implant by weight, the ester end poly(D,L-lactide-co-glycolide) constitutes 36 to 44% of the implant by weight, and wherein the polyethylene glycol 3350 constitutes 3.5 to 6.5% of the implant by weight, wherein the inherent viscosity of each of the poly(D,L-lactide) and poly(D,L-lactide-co-glycolide) polymers is determined for a 0.1% solution of the polymer in chloroform at 25°C.

[00055b] Another embodiment of the present invention is the use of a prostamide in the manufacture of a medicament for reducing ocular pressure in an eye of a mammal, wherein the medicament is to be provided by a biodegradable intraocular implant as disclosed herein placed in an eye of the mammal.

[00055c] Another embodiment of the present invention is a method for making a biodegradable intraocular implant as disclosed herein, the method comprising mixing the prostamide with the poly(D,L-lactide) and poly(D,L-lactide-co-glycolide) polymers and polyethylene glycol 3350, extruding the mixture to form a filament, followed by cutting the filament to length suitable for placement in the anterior chamber or vitreous body of an eye to thereby form an intraocular implant.

[00055d] Another embodiment of the present invention is a biodegradable intracameral implant for reducing intraocular pressure (IOP) in an eye, the implant comprising a biodegradable polymer matrix, polyethylene glycol 3350, and a prostamide as the active agent, wherein the prostamide and polyethylene glycol 3350 are associated with the biodegradable polymer matrix, which comprises

e) an ester end poly(D,L-lactide) having an inherent viscosity of 0.25-0.35 dl/g,

f) an acid end poly(D,L-lactide) having an inherent viscosity of 0.16-0.24 dl/g, and

g) an ester end poly(D,L-lactide-co-glycolide) having an inherent viscosity of 0.16-0.24 dl/g and a D,L-lactide to glycolide molar ratio of about 75:25;

wherein the prostamide constitutes 18 to 22% of the implant by weight, the ester end poly(D,L-lactide) constitutes 18 to 22% of the implant by weight, the acid end poly(D,L-lactide) constitutes 13.5 to 16.5% of the implant by weight, the ester end poly(D,L-lactide-co-glycolide) constitutes 36 to 44% of the implant by weight, and wherein the polyethylene glycol 3350 constitutes 3.5 to 6.5% of the implant by weight, wherein the inherent viscosity of each of the poly(D,L-lactide) and poly(D,L-lactide-co-glycolide) polymers is determined for a 0.1% solution of the polymer in chloroform at 25°C.

[00054e] Another embodiment of the present invention is use of a prostamide in the manufacture of a medicament for reducing ocular pressure in an eye of a mammal, wherein the medicament is to be provided by a biodegradable intracameral implant as described herein placed in an eye of the mammal.

[00054f] Another embodiment of the present invention is an apparatus for delivering a biodegradable intracameral implant into the eye of a patient, the apparatus comprising an intracameral implant as described herein, an elongate housing and a cannula extending longitudinally from the housing, the cannula having a proximal end, a distal sharp end, and a

lumen extending therethrough, the lumen having an inner diameter sufficient to receive the intraocular implant and permit translation of the implant through the lumen and into the eye of the patient.

[00054g] Another embodiment of the present invention is a method for making a biodegradable intracameral implant as described herein, the method comprising mixing the prostamide with the poly(D,L-lactide) and poly(D,L-lactide-co-glycolide) polymers and polyethylene glycol 3350, extruding the mixture to form a filament, followed by cutting the filament to length suitable for placement in the anterior chamber or vitreous body of an eye to thereby form an intraocular implant.

BRIEF DESCRIPTION OF THE DRAWINGS

[00056] FIG. 1 shows the in vitro cumulative release of bimatoprost (as a percent of the total amount of bimatoprost loaded in the implant) over time from an extruded implant having either Formulation 1 or Formulation 2 (see Table 1), following placement of the implant in 0.01 M phosphate buffered saline (pH 7.4) at 37°C. Each data point represents the average of 3 to 4 replicate samples. The implants in this study each weighed about 50 μg and had a length of about 1.05 mm and a diameter of about 200 μm.

[00057] FIG. 2A and B show the change in diameter and length (i.e., the swelling) of an extruded implant having either Formulation 1 or Formulation 2 over time in 0.01 M phosphate buffered saline (pH 7.4) at 37°C. The starting weight of the implants was about 50 μg, and the initial length and diameter of the implants in these studies were about 1.05 mm and about 200 μm, respectively.

[00058] FIG. 3 shows the swelling and degradation of extruded implants having either Formulation 1 or Formulation 2 in vitro over time following placement of the implants in phosphate buffered saline (pH 7.4) at 37°C. The implant mages were recorded at a magnification of 150X at various time points and the lengths and diameters were measured. Each implant was initially 1.05 mm in length and 200 μm in diameter and the starting total weight of each implant was about 50 μg.

CLAIMS

What is claimed is:

1. A biodegradable intracameral implant for reducing intraocular pressure (IOP) in an eye, the implant comprising a biodegradable polymer matrix, polyethylene glycol 3350, and a prostamide as the active agent, wherein the prostamide and polyethylene glycol 3350 are associated with the biodegradable polymer matrix, which comprises

    'a) an ester end poly(D,L-lactide) having an inherent viscosity of 0.25-0.35 dl/g,

    b) an acid end poly(D,L-lactide) having an inherent viscosity of 0.16-0.24 dl/g, and

    c) an ester end poly(D,L-lactide-co-glycolide) having an inherent viscosity of 0.16-0.24 dl/g and a D,L-lactide to glycolide molar ratio of about 75:25;

    wherein the prostamide constitutes 18 to 22% of the implant by weight, the ester end poly(D,L-lactide) constitutes 18 to 22% of the implant by weight, the acid end poly(D,L-lactide) constitutes 13.5 to 16.5% of the implant by weight, the ester end poly(D,L-lactide-co-glycolide) constitutes 36 to 44% of the implant by weight, and wherein the polyethylene glycol 3350 constitutes 3.5 to 6.5% of the implant by weight, wherein the inherent viscosity of each of the poly(D,L-lactide) and poly(D,L-lactide-co-glycolide) polymers is determined for a 0.1% solution of the polymer in chloroform at 25°C.

2. A biodegradable intracameral implant according to claim 1, wherein the prostamide constitutes 20% of the implant by weight, the ester end poly(D,L-lactide) constitutes 20% of the implant by weight, the acid end poly(D,L-lactide) constitutes 15% of the implant by weight, the ester end poly(D,L-lactide-co-glycolide) constitutes 40% of the implant by weight, and wherein the polyethylene glycol 3350 constitutes 5% of the implant by weight.

3. The implant of claim 1 or claim 2, wherein the implant is rod-shaped and is formed by a hot-melt extrusion process and wherein the implant is 150 μm to 300 μm in diameter or width, 0.50 mm to 2.5 mm in length, and 30 μg to 100 μg in total weight.

7. The implant of any one of claims 1-5, wherein the prostamide is bimatoprost.

8. Use of a prostamide in the manufacture of a medicament for reducing ocular pressure in an eye of a mammal, wherein the medicament is to be provided by a biodegradable intracameral implant according to claim 1 or claim 2 placed in an eye of the mammal.

9. The use of claim 8, wherein the mammal is a human patient that has elevated intraocular pressure, ocular hypertension, or glaucoma.

10. The use of claim 8 or claim 9, wherein the implant is to be placed in the anterior chamber of an eye of the patient.

11. The use of any one of claims 8-10, wherein the implant is effective for reducing intraocular pressure in the eye for at least two months after placement in the anterior chamber of the eye.

12. The use of any one of claims 8-11, wherein the prostamide is bimatoprost.

13. The use of any one of claims 8-12, wherein the implant is formed by an extrusion process and wherein the implant is 150 to 300 μm in diameter or width, 0.50 to 2.5 mm in length, and 30 to 100 μg in total weight.

14. The use of any one of claims 8-13, wherein the implant does not contact the corneal endothelium after placement in the anterior chamber of the eye.

15. The use of any one of claims 8-14, wherein the implant is to be placed in the eye(s) using an intraocular delivery apparatus, the apparatus comprising an elongate housing and a cannula extending longitudinally from the housing, the cannula having a proximal end and a distal sharp end and having a lumen extending therethrough, the lumen having an inner diameter

sufficient to receive the implant and permit translation of the implant through the lumen and into the eye of the patient.

16. An apparatus for delivering a biodegradable intracameral implant into the eye of a patient, the apparatus comprising an intracameral implant according to claim 1, an elongate housing and a cannula extending longitudinally from the housing, the cannula having a proximal end, a distal sharp end, and a lumen extending therethrough, the lumen having an inner diameter sufficient to receive the intraocular implant and permit translation of the implant through the lumen and into the eye of the patient.

17. The apparatus of claim 16, wherein the cannula is a 25 gauge, 26 gauge, 27 gauge, 28 gauge, 29 gauge, or 30 gauge needle.

18. A method for making a biodegradable intracameral implant according to claim 1, the method comprising mixing the prostamide with the poly(D,L-lactide) and poly(D,L-lactide-co-glycolide) polymers and polyethylene glycol 3350, extruding the mixture to form a filament, followed by cutting the filament to length suitable for placement in the anterior chamber or vitreous body of an eye to thereby form an intraocular implant.