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 25ºC.

[00055a] Another embodiment of the present invention is a use of a biodegradable polymer matrix, polyethylene glycol 3350, and bimatoprost, wherein the bimatoprost and polyethylene glycol 3350 are associated with the biodegradable polymer matrix in the manufacture of a biodegradable intraocular implant for reducing ocular pressure in an eye of a patient, wherein the biodegradable intraocular implant is to be injected into an eye of a patient in need thereof; and wherein the eye is to be treated after injection of the biodegradable intraocular implant into the eye, wherein the biodegradable intraocular implant swells during the treatment, and wherein the biodegradable intraocular implant reaches a maximum swell size by about 2 months and contracts in size after the about 2 months.

[00055b] Another embodiment of the present invention is a use of a biodegradable polymer matrix, polyethylene glycol 3350, and bimatoprost in the manufacture of a biodegradable intraocular implant for reducing ocular pressure in an eye of a patient, wherein the bimatoprost 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 bimatoprost comprises 18 to 22% of the biodegradable intraocular implant by weight, the ester end poly(D,L-lactide) comprises 18 to 22% of the biodegradable intraocular

implant by weight, the acid end poly(D,L-lactide) comprises 13.5 to 16.5% of the biodegradable intraocular implant by weight, the ester end poly(D,L-lactide-co-glycolide) comprises 36 to 44% of the biodegradable intraocular implant by weight, and wherein the polyethylene glycol 3350 comprises 3.5 to 6.5% of the biodegradable intraocular 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; and

wherein the biodegradable intraocular implant is to be injected into a posterior chamber of an eye of a patient in need thereof.

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. Use of a biodegradable polymer matrix, polyethylene glycol 3350, and bimatoprost, wherein the bimatoprost and polyethylene glycol 3350 are associated with the biodegradable polymer matrix in the manufacture of a biodegradable intraocular implant for reducing ocular pressure in an eye of a patient, wherein the biodegradable intraocular implant is to be injected into an eye of a patient in need thereof; and

wherein the eye is to be treated after injection of the biodegradable intraocular implant into the eye, wherein the biodegradable intraocular implant swells during the treatment, and wherein the biodegradable intraocular implant reaches a maximum swell size by about 2 months and contracts in size after the about 2 months.

2. The use of claim 1, wherein the biodegradable polymer matrix 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 bimatoprost comprises 18 to 22% of the biodegradable intraocular implant by weight, the ester end poly(D,L-lactide) comprises 18 to 22% of the biodegradable intraocular implant by weight, the acid end poly(D,L-lactide) comprises 13.5 to 16.5% of the biodegradable intraocular implant by weight, the ester end poly(D,L-lactide-co-glycolide) comprises 36 to 44% of the biodegradable intraocular implant by weight, and wherein the polyethylene glycol 3350 comprises 3.5 to 6.5% of the biodegradable intraocular 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.

3. The use of claim 2, wherein the bimatoprost comprises 20% of the biodegradable intraocular implant by weight, the ester end poly(D,L-lactide) comprises 20% of the biodegradable intraocular implant by weight, the acid end poly(D,L-lactide) comprises 15% of the biodegradable intraocular implant by weight, the ester end poly(D,L-lactide-co-glycolide)

comprises 40% of the biodegradable intraocular implant by weight, and wherein the polyethylene glycol 3350 comprises 5% of the biodegradable intraocular implant by weight.

4. The use of claim 1, wherein the maximum swell size of the biodegradable intraocular implant is no greater than 4 times an initial diameter of the biodegradable intraocular implant prior to injection into the eye.

5. The use of claim 1, wherein the maximum swell size of the biodegradable intraocular implant is less than 3 times an initial diameter of the biodegradable intraocular implant prior to injection into the eye.

6. The use of claim 1, wherein the maximum swell size of the biodegradable intraocular implant is no greater than 2 times an initial length of the biodegradable intraocular implant prior to injection into the eye.

7. The use of claim 1, wherein the biodegradable intraocular implant is rod-shaped and is formed by a hot-melt extrusion process and wherein, prior to injection in the eye, the biodegradable intraocular 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.

8. The use of claim 1, wherein the biodegradable intraocular implant is effective for reducing intraocular pressure in an eye for the about 2 months or longer after injection into the eye.

9. The use of claim 1, wherein the patient has one or more of elevated intraocular pressure, ocular hypertension, or glaucoma.

10. The use of claim 1, wherein the biodegradable intraocular implant is to be placed into the eye 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 biodegradable intraocular implant and permit translation of the biodegradable intraocular implant through the lumen and into the eye of the patient.

11. The use of claim 1, wherein treatment of the eye comprises a release of a therapeutically effective amount of the bimatoprost at a nearly linear or constant rate for at least the 2 months.

12. The use of claim 1, wherein the biodegradable intraocular implant is to be injected into the anterior chamber of the eye.

13. The use of claim 12, wherein the biodegradable intraocular implant does not contact the corneal endothelium after placement in the anterior chamber of the eye.

14. The use of claim 1, wherein the biodegradable intraocular implant is to be injected into the posterior chamber of the eye.

15. The use of claim 14, wherein the biodegradable intraocular implant is to be injected into a ciliary sulcus of the eye.

16. Use of a biodegradable polymer matrix, polyethylene glycol 3350, and bimatoprost in the manufacture of a biodegradable intraocular implant for reducing ocular pressure in an eye of a patient, wherein the bimatoprost 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 bimatoprost comprises 18 to 22% of the biodegradable intraocular implant by weight, the ester end poly(D,L-lactide) comprises 18 to 22% of the biodegradable intraocular implant by weight, the acid end poly(D,L-lactide) comprises 13.5 to 16.5% of the biodegradable intraocular implant by weight, the ester end poly(D,L-lactide-co-glycolide) comprises 36 to 44%

of the biodegradable intraocular implant by weight, and wherein the polyethylene glycol 3350 comprises 3.5 to 6.5% of the biodegradable intraocular 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; and

wherein the biodegradable intraocular implant is to be injected into a posterior chamber of an eye of a patient in need thereof.

17. The use of claim 16, wherein the eye is to be further treated after injection of the biodegradable intraocular implant in the posterior chamber of the eye, wherein the biodegradable intraocular implant swells during the treating, and wherein the biodegradable intraocular implant reaches a maximum swell size by about 2 months and contracts in size after the about 2 months.