Claims

1. A biodegradable ocular implant for sustained drug delivery, comprising a first layer comprising a first biodegradable polymer, wherein the first layer contains a drug dispersed or dissolved therein.

2. The biodegradable ocular implant of claim 1, further comprising at least one top layer comprising a second biodegradable polymer, wherein the at least one top layer is arranged on top of the first layer.

3. The biodegradable ocular implant of claim 2, further comprising at least one bottom layer comprising a third biodegradable polymer, wherein the first layer is arranged on top of the at least one bottom layer to thereby form a sandwich assembly having the first layer arranged between the at least one top layer and the at least one bottom layer.

4. The biodegradable ocular implant of claim 3, wherein the at least one top layer, or the at least one bottom layer, or both, contains a drug dispersed or dissolved in the respective layer.

5. The biodegradable ocular implant of claim 1, wherein the drug is uniformly dissolved in the polymer matrix of the respective layer.

6. The biodegradable ocular implant of claim 1, wherein the drug is dispersed at the surface of the respective layer.

7. The biodegradable ocular implant of claim 3, wherein the first biodegradable polymer, the second biodegradable polymer, and the third biodegradable polymer are the same.

8. The biodegradable ocular implant of claim 3, wherein the first biodegradable polymer, the second biodegradable polymer, and the third biodegradable polymer are different.

9. The biodegradable ocular implant of claim 1, wherein each biodegradable polymer is independently selected from the group consisting of polylactide (PLA), poly-L-lactide (PLLA), poly-D-lactide (PDLA), poly(L-lactide-co-glycolide) (PLGA), polyethylene glycol (PEG), polypropylene glycol (PPG), polycaprolactone (PCL), polyesteramide (PEA), a PLLA copolymer, a PLGA copolymer, a PDLA copolymer, a PCL copolymer, a PEA copolymer, a PEG copolymer, a PPG copolymer, and mixtures thereof.

10. The biodegradable ocular implant of claim 9, wherein the biodegradable polymer is a copolymer of PLA and PCL.

11. The biodegradable ocular implant of claim 10, wherein the molar ratio PLA:PCL is between about 90:10 and about 10:90.

12. The biodegradable ocular implant of claim 11, wherein the molar ratio PLA:PCL is 70:30.

13. The biodegradable ocular implant of claim 9, wherein the biodegradable polymer is a triblock copolymer comprising PLA as end-blocks and a middle block selected from the group consisting of PCL, a copolymer of PCL and trimethylene carbonate (TMC), a copolymer of PCL and PLGA.

14. The biodegradable ocular implant of claim 9, wherein the biodegradable polymer is a multiblock copolymer of polylactide-caprolactone (PLC) and PLA.

15. The biodegradable ocular implant of claim 9, wherein the biodegradable polymer is a polyurethane type copolymer formed from di-isocyanates and butanediol, and soft segments selected from PCL/PLA and PCL/TMC.

16. The biodegradable ocular implant of claim 3, wherein the at least one top layer or the at least one bottom layer is impermeable for the drug to provide for a directional release of the drug.

17. The biodegradable ocular implant of claim 2, wherein each of the biodegradable polymers of the different layers has a different degradation rate.

18. The biodegradable ocular implant of claim 1, wherein the drug comprises an ocular drug.

19. The biodegradable ocular implant of claim 1, wherein the drug is selected from the group consisting of an immunosuppressant agent, an antibiotic, an anti-inflammatory agent, an anti-scarring agent, an anti-glaucoma medication, a prostaglandin analogue, an anti-steroidal agents, an anti-microbial agent, an anti-fibrotic antibody, and a small interfering ribonucleic acid (siRNA) molecule against fibrosis.

20. The biodegradable ocular implant of claim 19, wherein the drug is betamethasone, prednisolone, dexmethasone, cyclosporine, latanoprost and derivates, timolol maleate, valproic acid, or ciproflaxin.

21. The biodegradable ocular implant of claim 1, wherein each respective layer comprises 70-98 wt % (based on total weight of the layer) of the polymer matrix and 2-30 wt % of the drug.

22. The biodegradable ocular implant of claim 1, wherein the modulus of the biodegradable ocular implant is between about 0.1 MPa and about 1,000 MPa.

23. The biodegradable ocular implant of claim 1, wherein the elongation-to-break point of the biodegradable ocular implant is at least 300%.

24. The biodegradable ocular implant of claim 1, further comprising an excipient or plasticizer.

25. The biodegradable ocular implant of claim 24, wherein the excipient or plasticizer is PG, triethyl citrate (TEC) or glycerol.

26. The biodegradable ocular implant of claim **1**, wherein the biodegradable ocular implant is a multi-layer film comprising the first layer, the multi-layer film being configured to be implanted within a subconjunctival space of an eye of a subject.

27. The biodegradable ocular implant of claim **26**, wherein the biodegradable ocular implant is configured to resume a desired shape after insertion into the subconjunctival space of the eye of the subject.

28. The biodegradable ocular implant of claim **27**, wherein the desired shape comprises a curved shape or a convex shape.

29. The biodegradable ocular implant of claim **27**, wherein the biodegradable ocular implant is configured to resume the desired shape when exposed to a temperature of about 37° C.

30. The biodegradable ocular implant of claim **1**, wherein each of the layers has a thickness of about 0.1 micron to about 10 microns.

31. The biodegradable ocular implant of claim **1**, wherein the biodegradable ocular implant has an overall thickness of about 1 mm to about 2 mm.

32. A method of forming a biodegradable ocular implant for sustained drug delivery, comprising:

(a) providing a first layer comprising a first biodegradable polymer; and

(b) loading the first biodegradable polymer with a drug.

33. The method of claim **32**, wherein providing the first layer comprises:

(a) dissolving the first biodegradable polymer in a suitable solvent to form a first solution; and

(b) evaporating the solvent to obtain the first layer.

34. The method of claim 33, wherein loading comprises adding the drug to the first solution prior to evaporating the solvent.

35. The method of claim 32, wherein loading comprises immersing the first layer in a solution containing the drug.

36. The method of claim 33, wherein loading comprises simultaneously dissolving the drug and the first biodegradable polymer in the solvent prior to evaporating the solvent.

37. The method of claim 32, further comprising:

(a) dissolving a second biodegradable polymer with a suitable solvent to form a second solution;

(b) casting the second solution on top of the first layer; and

(c) evaporating the solvent to form a top layer.

38. The method of claim 32, further comprises forming a bottom layer on which the first layer is arranged, comprising:

(a) dissolving a third biodegradable polymer with a suitable solvent to form a third solution;

(b) evaporating the solvent to form a bottom layer; and

(c) depositing the first layer on top of the bottom layer.

39. The method of claim 38, wherein the first layer, or the top layer, or the bottom layer is formed over a curved-surfaced member.

40. The method of claim 39, wherein the curved-surfaced member comprises a tubular scaffold or a cylinder.

41. The method of claim 39, further comprising cutting the respective layer radially to obtain a convex shape.

42. The method of claim 38, wherein the first layer, or the top layer, or the bottom layer is casted into a convex mold to obtain a convex shape.

43. The method of claim **38**, wherein the first layer, or the top layer, or the bottom layer is casted into a flat sheet, followed by heat-shaping the flat sheet into a convex shape.

44. The method of claim **43**, wherein the biodegradable ocular implant comprises an outermost layer and wherein the heat-shaping step is applied to the outermost layer at its glass transition temperature (Tg).

45. A biodegradable ocular implant for sustained drug delivery, comprising a first layer comprising a first biodegradable polymer matrix capable of containing a drug dispersed therein.

46. A multi-layered biodegradable ocular implant for sustained drug delivery, comprising:

(a) a first layer comprising a first biodegradable polymer capable of containing a drug dispersed therein; and

(b) at least one other layer comprising a second biodegradable polymer arranged adjacent the first layer.

47. The multi-layered biodegradable ocular implant of claim **46**, wherein the second biodegradable polymer is capable of containing a drug dispersed therein.

48. The method of claim **32**, wherein the biodegradable ocular implant is a multi-layer film comprising the first layer, and the method comprises forming the multi-layer film to be configured to be implanted within a subconjunctival space of an eye of a subject.

49. The biodegradable ocular implant of claim **45**, wherein the biodegradable ocular implant is a multi-layer film comprising the first layer, the multi-layer film being configured to be implanted within a subconjunctival space of an eye of a subject.

50. The multi-layered biodegradable ocular implant of claim **46**, wherein the multi-layered biodegradable ocular implant is a multi-player film comprising the first layer and the at least one other layer, the multi-layer film being configured to be implanted within a subconjunctival space of an eye of a subject.