provide a convenient way to prevent leakage from insertion site, which can lead to discomfort and loss of medicament. This can prolong treatment as well as increase costs associated with the treatment.

[1011] Thus, a need exists for improved devices and methods, which can assist in determining if the needle is at the correct depth, can facilitate injection of the medicament into ocular tissue, and/or can prevent leakage of ocular fluids and/or medicament form the insertion site.

Summary of the Invention

[1012] The embodiments described herein relate generally to the field of ophthalmic therapies and more particularly to the use of a microneedle for delivery and/or removal of a substance, such as a fluid therapeutic agent into and/or from ocular tissues for treatment of the eye.

[1012a] According to a first aspect of the present invention, there is provided an apparatus, comprising: a housing configured to receive a portion of a medicament container; a hub, the hub coupled to the housing and defining a passageway configured to receive a puncture member therethrough, the hub having a distal end surface, the distal end surface of the hub configured to contact a target surface of a target tissue when a substance is conveyed through the puncture member; and an actuation rod, the actuation rod configured to be coupled to the medicament container, the actuation rod and the puncture member collectively configured such that (1) a distal end portion of the actuation rod moves within the medicament container in response to a force on the actuation rod when a distal end portion of the puncture member is disposed within a first region of the target tissue and the actuation rod is coupled to the medicament container, and (2) movement of the distal end portion of the actuation rod within the medicament container in response to the force on the actuation rod is limited when the distal end portion of the puncture member is disposed within a second region of the target tissue and the actuation rod is coupled to the medicament container, the force having a magnitude less than a threshold value.

[1012b] According to a second aspect of the present invention, there is provided an apparatus, comprising: a housing configured to receive a portion of a medicament container; and a hub coupled to the housing, the hub defining a passageway configured to receive a puncture member therethrough, the hub having a convex distal end surface, the distal end

surface of the hub configured to contact a target surface of a target tissue when a substance is conveyed through the puncture member.

[1012c] According to a third aspect of the present invention, there is provided an apparatus, comprising: a housing configured to receive a portion of a medicament container; a hub coupled to the housing, the hub defining a passageway configured to receive a puncture member therethrough, the hub having a distal end surface, the distal end surface of the hub configured to contact a target surface of a target tissue when a substance is conveyed through the puncture member; and the puncture member fixedly coupled to the hub such that the hub moves with the puncture member when the puncture member is moved relative to the target surface.

[1013] In some embodiments, an apparatus includes a housing configured to be coupled to a medicament container. The medicament container is configured to be coupled to a needle. An injection assembly is disposed within the housing and includes an energy storage member and an actuation rod. A distal end portion of the actuation rod is configured to be disposed within the medicament container. The energy storage member is configured to produce a force on a proximal end portion of the actuation rod. The force is sufficient to move the distal end portion of the actuation rod within the medicament container to convey at least a portion of a substance from the medicament container via the needle when a distal tip of the needle is disposed within a first region of a target location. Furthermore, the force is insufficient to move the distal end portion of the actuation rod within the medicament container when the distal tip of the needle is disposed within a second region of the target location. In some embodiments, the first region of the target location has a first density and the second region of the target location has a second density, higher than the first density. In some embodiments, the first region of the target location produces a first backpressure and the second region of the target location produces a second backpressure, higher than the first backpressure.

[1014] In some embodiments, an apparatus includes a housing configured to receive a portion of a medicament container, and an adjustment member. A proximal end portion of

Claims

1. An apparatus, comprising:

a housing configured to be coupled to a medicament container, the medicament container configured to be coupled to a needle; and

an injection assembly disposed within the housing, the injection assembly including an energy storage member and an actuation rod, a distal end portion of the actuation rod configured to be disposed within the medicament container, the energy storage member configured to produce a force on a proximal end portion of the actuation rod, the force sufficient to move the distal end portion of the actuation rod within the medicament container to convey at least a portion of a substance from the medicament container via the needle when a distal tip of the needle is disposed within a first region of a target location, the force insufficient to move the distal end portion of the actuation rod within the medicament container when the distal tip of the needle is disposed within a second region of the target location.

2. The apparatus of claim 1, wherein:

the first region of the target location has a first density; and

the second region of the target location has a second density, the second density higher than the first density.

3. The apparatus of claim 1, wherein:

the first region of the target location produces a first backpressure on the distal tip of the needle; and

the second region of the target location produces a second backpressure on the distal tip of the needle, the second backpressure higher than the first backpressure.

4. The apparatus of claim 1, wherein:

the target location is an eye;

the first region is a suprachoroidal space of the eye; and

the second region is a sclera of the eye.

5. The apparatus of claim 1, wherein the force is between about 2 N and about 6 N.

6. The apparatus of claim 1, wherein the actuation rod and the medicament container are collectively configured such that the force produces an injection pressure within the medicament container of between about 100 kPa and about 500 kPa.

7. The apparatus of claim 1, wherein the proximal end portion of the actuation rod moves relative to the housing to move the distal end portion of the actuation rod within the medicament container when the distal tip of the needle is disposed within the first region of the target location.

8. The apparatus of claim 1, wherein:

the injection assembly includes a release member configured to selectively limit movement of the actuation rod relative to the housing; and

the housing is configured to move relative to the medicament container to move the distal end portion of the actuation rod within the medicament container independently from the force.

9. The apparatus of claim 1, wherein:

the injection assembly includes a release member configured to move between a first position and a second position, the release member configured to release the energy storage member when moved from the first position to the second position.

10. The apparatus of claim 1, wherein the injection assembly includes a guide rod fixedly coupled within the housing, the actuation rod configured to slide about the guide rod when the energy storage member is released.

11. The apparatus of claim 1, wherein the energy storage member is any one of a spring, a compressed gas container or a container containing a propellant.

12. The apparatus of claim 1, further comprising:

the medicament container, the medicament container containing at least one of a VEGF, a VEGF inhibitor or a combination thereof.

13. An apparatus, comprising:

a housing configured to receive at least a portion of a medicament container, the medicament container configured to be coupled to a needle; and

an injection assembly disposed within the housing, the injection assembly including an energy storage member, an actuation rod and a release member, a distal end portion of the actuation rod configured to be disposed within the medicament container, the release member configured to maintain a position of the actuation rod relative to the housing when the release member is in a first position such that movement of the housing relative to the medicament container moves the distal end portion of the actuation rod within the medicament container, the release member configured to release the actuation rod when moved from the first position to a second position such that a force produced by the energy storage member moves the distal end portion of the actuation rod relative to the housing and within the medicament container to convey at least a portion of a substance from the medicament container via the needle.

14. The apparatus of claim 13, wherein the force is sufficient to move the distal end portion of the actuation rod within the medicament container when a distal tip of the needle is disposed within a first region of a target location, the force being insufficient to move the distal end portion of the actuation rod within the medicament container when the distal tip of the needle is disposed within a second region of the target location.

15. The apparatus of claim 14, wherein:

the first region of the target location has a first density; and

the second region of the target location has a second density, the second density higher than the first density.

16. The apparatus of claim 14, wherein:

the target location is an eye;

the first region is a suprachoroidal space of the eye; and

the second region is a sclera of the eye.

17. The apparatus of claim 13, wherein the force is between about 2 N and about 6 N.

18. The apparatus of claim 13, wherein the injection assembly includes a guide rod fixedly coupled within the housing, the actuation rod configured to slide about the guide rod when the actuation rod is released.

19. The apparatus of claim 13, wherein the energy storage member is any one of a spring, a compressed gas container or a container containing a propellant.

20. A method, comprising:

inserting a distal tip of a needle of a medical injector a first distance into a target tissue, the medical injector including a medicament container and an injection assembly, the medicament container in fluid communication with the needle, the injection assembly including an actuation rod and an energy storage member, the energy storage member configured to produce a force on a proximal end portion of the actuation rod;

releasing the actuation rod of the injection assembly to allow a distal end portion of the actuation rod to move within the medicament container in response to the force; and

inserting, after the releasing, the distal tip of the needle of the medical injector a second distance into the target tissue if the distal end portion of the actuation rod moves less than a threshold injection distance within the medicament container in response to the force, the second distance greater than the first distance.

21. The method of claim 20 wherein the injection distance is less than about 1 cm.

22. The method of claim 20, wherein the distal end portion of the actuation rod moves a first injection distance within the medicament container in response to the force, the method further comprising:

moving the injection assembly relative to the medicament container to move the distal end portion of the actuation rod a second injection distance within the medicament container, the second injection distance greater than the first injection distance.

23. The method of claim 20, wherein:

the target tissue is an eye; and

the inserting the distal tip of the needle of the medical injector the second distance into the eye includes inserting at least a portion of the distal tip into a suprachoroidal space of the eye.

24. The method of claim 20, wherein:

the target tissue is an eye; and

the inserting the distal tip of the needle of the medical injector the second distance into the eye includes contacting a surface of the eye with a hub coupled to the needle.

25. An apparatus, comprising:

a housing configured to receive a portion of a medicament container; and

an adjustment member, a proximal end portion of the adjustment member configured to be coupled to the medicament container, a distal end portion of the adjustment member coupled to a needle, the adjustment member movably disposed within the housing such that when the adjustment member is rotated relative to the housing, the needle is moved through a plurality of discrete increments along a longitudinal axis of the housing.

26. The apparatus of claim 25, wherein the adjustment member defines a lumen configured to place the medicament container in fluid communication with the needle.

27. The apparatus of claim 25, wherein the proximal end portion of the adjustment member includes a flange configured to be removably coupled the medicament container.

28. The apparatus of claim 25, wherein each discrete increment from the plurality of discrete increments is associated with a corresponding detent from a plurality of detents defined by at least one of the adjustment member or the housing.

29. The apparatus of claim 25, wherein:

the adjustment member defines a plurality of detents; and

the housing includes a protrusion configured to be removably disposed within each detent from the plurality of detents when the adjustment member is rotated relative to the housing to move the needle through the plurality of discrete increments.

30. The apparatus of claim 25, wherein the adjustment member defines a plurality of detents, the apparatus further comprising:

a bearing coupled within the housing, the bearing configured to be removably disposed within each detent from the plurality of detents when the adjustment member is

rotated relative to the housing to move the needle through the plurality of discrete increments; and

a bias member configured to maintain the bearing within a detent from the plurality of detents.

31. The apparatus of claim 25, further comprising:

a lock member removably coupled to the housing, the lock member configured to engage the adjustment member to limit movement of the adjustment member relative to the housing.

32. The apparatus of claim 25, further comprising:

a hub coupled to the housing, the hub defining a passageway configured to receive the needle therethrough such that a distal end portion of the needle extends past a distal end surface of the hub by a distance that changes when the needle is moved through the plurality of discrete increments along the longitudinal axis of the housing.

33. The apparatus of claim 32, wherein the hub is configured to limit movement of adjustment member within the housing.

34. The apparatus of claim 25, wherein:

the housing defines a window; and

the adjustment member includes an indication portion visible through the window of the housing, the indication portion configured to indicate a distance that the needle extends beyond the housing.

35. An apparatus, comprising:

a housing configured to receive a portion of a medicament container; and

an adjustment member, a proximal end portion of the adjustment member configured to be coupled to the medicament container, a distal end portion of the adjustment member coupled to a needle, the adjustment member defining a plurality of detents,

a protrusion of the housing configured to be removably disposed within each detent from the plurality of detents when the adjustment member is moved relative to the housing to move the needle relative to the housing through a plurality of discrete increments.

36. The apparatus of claim 35, wherein the protrusion is a bearing movably coupled within the housing, the bearing configured to be removably disposed within each detent from the plurality of detents when the adjustment member is moved relative to the housing to move the needle through the plurality of discrete increments, the apparatus further comprising:

a bias member configured to maintain the bearing within a detent from the plurality of detents.

37. The apparatus of claim 35, further comprising:

a lock member removably coupled to the housing, the lock member configured to engage the adjustment member to limit movement of the adjustment member relative to the housing.

38. The apparatus of claim 35, further comprising:

a hub coupled to the housing, the hub defining a passageway configured to receive the needle therethrough such that a distal end portion of the needle extends past a distal end surface of the hub by a distance that changes when the needle is moved through the plurality of discrete increments.

39. The apparatus of claim 38, wherein the hub is configured to limit movement of adjustment member within the housing.

40. The apparatus of claim 35, wherein:

the housing defines a window; and

the adjustment member includes an indication portion visible through the window of the housing, the indication portion configured to indicate a distance that the needle extends beyond the housing.

41. An apparatus, comprising:

a hub configured to be coupled to a medical injector, the hub defining a passageway configured to receive a needle therethrough, the hub having a convex distal end surface, the distal end surface configured to contact a target surface of a target tissue when a substance is conveyed through the needle into the target tissue.

42. The apparatus of claim 41, wherein the distal end surface includes a sealing portion configured to define a substantially fluid-tight seal with the target surface when the distal end surface is in contact with the target surface.

43. The apparatus of claim 41, wherein the distal end surface includes a sealing portion configured to define a substantially fluid-tight seal with the target surface when the distal end surface is in contact with the target surface, the sealing portion being symmetrical about a centerline of the passageway.

44. The apparatus of claim 41, wherein the distal end surface is configured to deform the target surface when the distal end surface is in contact with the target surface.

45. The apparatus of claim 41, wherein at least a portion of the distal end surface has a hemispherical shape.

46. The apparatus of claim 41, wherein the target tissue is an eye and the target surface is a conjunctiva of the eye.

47. The apparatus of claim 41, further comprising:

a needle adjustment mechanism, the needle adjustment mechanism configured to move the needle within the passageway such that a distal end portion the needle extends from the distal end surface of the hub by a predetermined amount.

48. The apparatus of claim 41, further comprising:

the needle, the needle being a microneedle movably disposed within the passageway.

49. A method, comprising:

inserting a distal end portion of a needle of a medical injector into a target tissue to define a delivery passageway within the target tissue;

placing a convex distal end surface of a hub of the medical injector into contact with a target surface of the target tissue to fluidically isolate the delivery passageway; and

conveying, after the placing, a substance into the target tissue via the needle.

50. The method of claim 49, wherein:

the inserting is performed such that a centerline of the delivery passageway and a surface line tangent to the target surface defines an angle of entry of between about 75 degrees and about 105 degrees.

51. The method of claim 49, wherein the inserting is performed such that a centerline of the needle is substantially normal to the target surface.

52. The method of claim 49, wherein the target tissue is an eye and the target surface is a conjunctiva of the eye.

53. The method of claim 52, wherein:

the delivery passage way extends through a sclera of the eye; and

the conveying includes conveying the substance into at least one of a suprachoroidal space or a lower portion of the sclera.

54. The method of claim 52, wherein the substance is at least one of a VEGF, a VEGF inhibitor or a combination thereof.

55. The method of claim 49, wherein the placing includes deforming the target surface.

56. The method of claim 49, wherein the distal end surface of the hub includes a sealing portion configured to define a substantially fluid-tight seal with the target surface, the sealing portion being symmetrical about a centerline of the needle.

57. The method of claim 49, wherein the delivery passage way extends through a sclera of the eye, the conveying includes conveying the substance into at least one of a suprachoroidal space or a lower portion of the sclera, the method further comprising:

adjusting, before the conveying, a length of the needle extending from the distal end surface of the hub.

58. A method, comprising:

inserting a distal end portion of a needle of a medical injector into a target tissue to define a delivery passageway within the target tissue, the inserting is performed such that a centerline of the needle is substantially normal to a target surface of the target tissue;

placing a distal end surface of a hub of the medical injector into contact with a target surface of the target tissue to fluidically isolate the delivery passageway; and

conveying, after the placing, a substance into the target tissue via the needle.

59. The method of claim 58, wherein:

the inserting is performed such that a centerline of the delivery passageway and a surface line tangent to the target surface defines an angle of entry of between about 75 degrees and about 105 degrees.

60. The method of claim 58, wherein the distal end surface of the hub includes a sealing portion configured to define a substantially fluid-tight seal with the target surface, the sealing portion being convex.

61. The method of claim 58, wherein the target tissue is an eye and the target surface is a conjunctiva of the eye.

62. The method of claim 61, wherein:

the delivery passage way extends through a sclera of the eye; and

the conveying includes conveying the substance into at least one of a suprachoroidal space or a lower portion of the sclera.

63. The method of claim 61, wherein the substance is at least one of a VEGF, a VEGF inhibitor or a combination thereof.

64. The method of claim 58, wherein the placing includes deforming the target surface.

Claims:

1. An apparatus, comprising:

a housing configured to receive a portion of a medicament container;

a hub, the hub coupled to the housing and defining a passageway configured to receive a puncture member therethrough, the hub having a distal end surface, the distal end surface of the hub configured to contact a target surface of a target tissue when a substance is conveyed through the puncture member; and

an actuation rod, the actuation rod configured to be coupled to the medicament container, the actuation rod and the puncture member collectively configured such that (1) a distal end portion of the actuation rod moves within the medicament container in response to a force on the actuation rod when a distal end portion of the puncture member is disposed within a first region of the target tissue and the actuation rod is coupled to the medicament container, and (2) movement of the distal end portion of the actuation rod within the medicament container in response to the force on the actuation rod is limited when the distal end portion of the puncture member is disposed within a second region of the target tissue and the actuation rod is coupled to the medicament container, the force having a magnitude less than a threshold value.

2. The apparatus of claim 1, wherein:

the threshold value is about 6N.

3. The apparatus of claim 1, wherein:

the force is between about 0.5N and about 2N.

4. The apparatus of claim 1, wherein:

the target tissue is an eye, the target surface is any one of a conjunctiva of the eye or a sclera of the eye,

the first region includes at least one of a suprachoroidal space, a lower portion of the sclera, a choroid of the eye, a subretinal space of the eye, or a retina of the eye,

the second region is an upper portion of a sclera of the eye.

5. The apparatus of claim 1, wherein:

the distal end surface of the hub includes a sealing portion configured to define a substantially fluid-tight seal with the target surface when the distal end surface is in contact with the target surface.

6. The apparatus of claim 1, wherein:

the distal end surface of the hub includes a sealing portion configured to define a substantially fluid-tight seal with the target surface when the distal end surface of the hub is in contact with the target surface, the sealing portion being symmetrical about a centerline of the passageway.

7. The apparatus of claim 1, wherein:

the target tissue is an eye, the target surface is any one of a conjunctiva of the eye or a sclera of the eye,

the distal end surface of the hub is configured to deform any one of (1) the conjunctiva of the eye, or (2) the sclera of the eye, when the distal end surface of the hub is in contact with the target surface.

8. The apparatus of claim 1, further comprising:

the puncture member, a centerline of the puncture member being substantially normal to a surface line tangent to the hub.

9. The apparatus of claim 1, wherein:

the substance is conveyed through the puncture member in response to movement of the actuation rod within the medicament container when the distal end portion of the puncture member is disposed within the first region of the target tissue and the actuation rod is coupled to the medicament container.

10. The apparatus of claim 1, wherein:

movement of the distal end portion of the actuation rod within the medicament container in response to the force on the actuation rod is limited when the distal end portion of the puncture

member is disposed within the second region of the target tissue and the actuation rod is coupled to the medicament container such that the substance is not conveyed to the second region of the target tissue.

11. An apparatus, comprising:

a housing configured to receive a portion of a medicament container; and

a hub coupled to the housing, the hub defining a passageway configured to receive a puncture member therethrough, the hub having a convex distal end surface, the distal end surface of the hub configured to contact a target surface of a target tissue when a substance is conveyed through the puncture member.

12. The apparatus of claim 11, wherein:

the distal end surface of the hub includes a sealing portion configured to define a substantially fluid-tight seal with the target surface when the distal end surface is in contact with the target surface.

13. The apparatus of claim 11, wherein:

the distal end surface of the hub includes a sealing portion configured to define a substantially fluid-tight seal with the target surface when the distal end surface of the hub is in contact with the target surface, the sealing portion being symmetrical about a centerline of the passageway.

14. The apparatus of claim 11, wherein:

the target tissue is an eye and the target surface is any one of a conjunctiva of the eye or a sclera of the eye.

15. The apparatus of claim 14, wherein:

the distal end surface of the hub is configured to deform any one of (1) the conjunctiva of the eye, (2) the sclera of the eye, (3) a choroid of the eye, or (4) a retina of the eye, when the distal end surface of the hub is in contact with the target surface.

16. The apparatus of claim 11, further comprising:

the puncture member, a centerline of the puncture member being substantially normal to a surface line tangent to the hub.

17. The apparatus of claim 11, further comprising:

an actuation rod at least partially disposed within the medicament container,

the medicament container, the actuation rod, and the puncture member collectively configured such that (1) a distal end portion of the actuation rod moves within the medicament container in response to a force on the actuation rod when a distal end portion of the puncture member is disposed within a first region of the target tissue, and (2) movement of the distal end portion of the actuation rod within the medicament container in response to the force on the actuation rod is limited when the distal end portion of the puncture member is disposed within a second region of the target tissue, the force having a magnitude less than a threshold value.

18. The apparatus of claim 17, wherein:

the threshold value is from about 2 N to about 6 N.

19. The apparatus of claim 17, wherein:

the target tissue is an eye, the target surface is any one of a conjunctiva of the eye or a sclera of the eye,

the first region includes at least one of a suprachoroidal space, a lower portion of the sclera, a choroid of the eye, a subretinal space of the eye, or a retina of the eye,

the second region is an upper portion of a sclera of the eye.

20. The apparatus of claim 17, wherein:

the target tissue is an eye and the target surface is a conjunctiva of the eye,

the distal end surface of the hub being configured to displace the conjunctiva towards a sclera of the eye in response to the force.

21. An apparatus, comprising:

a housing configured to receive a portion of a medicament container;

a hub coupled to the housing, the hub defining a passageway configured to receive a puncture member therethrough, the hub having a distal end surface, the distal end surface of the hub configured to contact a target surface of a target tissue when a substance is conveyed through the puncture member; and

the puncture member fixedly coupled to the hub such that the hub moves with the puncture member when the puncture member is moved relative to the target surface.

22. The apparatus of claim 21, wherein:

the distal end surface of the hub includes a sealing portion configured to define a substantially fluid-tight seal with the target surface when the distal end surface is in contact with the target surface.

23. The apparatus of claim 21, wherein:

the distal end surface of the hub includes a sealing portion configured to define a substantially fluid-tight seal with the target surface when the distal end surface of the hub is in contact with the target surface, the sealing portion being symmetrical about a centerline of the passageway.

24. The apparatus of claim 21, wherein:

the target tissue is an eye and the target surface is any one of a conjunctiva of the eye or a sclera of the eye.

25. The apparatus of claim 24, wherein:

the distal end surface of the hub is configured to deform any one of (1) the conjunctiva of the eye, (2) the sclera of the eye, (3) a choroid of the eye, or (4) a retina of the eye, when the distal end surface of the hub is in contact with the target surface.

26. The apparatus of claim 21, wherein:

a centerline of the puncture member is substantially normal to a surface line tangent to the hub.

27. The apparatus of claim 21, further comprising:

an actuation rod at least partially disposed within the medicament container,

the medicament container, the actuation rod, and the puncture member collectively configured such that (1) a distal end portion of the actuation rod moves within and relative to the medicament container in response to a force on the actuation rod when a distal end portion of the puncture member is disposed within a first region of the target tissue, and (2) movement of the distal end portion of the actuation rod within and relative to the medicament container in response to the force on the actuation rod is limited when the distal end portion of the puncture member is disposed within a second region of the target tissue, the force having a magnitude less than a threshold value.

28. The apparatus of claim 27, wherein:

the threshold value is from about 2 N to about 6 N.

29. The apparatus of claim 27, wherein:

the target tissue is an eye, the target surface is any one of a conjunctiva of the eye or a sclera of the eye,

the first region includes at least one of a suprachoroidal space, a lower portion of the sclera, a choroid of the eye, a subretinal space of the eye, or a retina of the eye,

the second region is an upper portion of a sclera of the eye.

30. The apparatus of claim 21, wherein:

at least a portion of the distal end surface of the hub has a hemispherical shape.