drug in the vitreous; and, if it is too short, it delivers into the sclera. The sclera is 10 times stiffer than the choroid and 200 times stiffer than the retina making it even more challenging to pierce the sclera without injecting into the vitreous. In some instances, a small volume (on the order of 100 microliters) of therapeutic needs to be injected into the suprachoroidal space, and it needs to be injected with sufficient force to displace the positive resistance of intraocular pressure pressing the choroid against the sclera to achieve a broad coverage of the posterior segment of the eye. This may be difficult to achieve using a conventional hand-held syringe.

[005] Accordingly, there is a need for an improved system and method for suprachoroidal drug delivery that precisely, consistently and safely targets the suprachoroidal space and provides broad coverage of the posterior segment of the eye.

SUMMARY

[006] According to some aspects of the present disclosure, there is provided an injection system comprising an injection assembly comprising a syringe barrel defining a lumen between a proximal end and a distal end and a second sealing element moveably disposed within the lumen to dispense an injection agent from an injection chamber defined in the syringe barrel, and a puncture element configured to deliver the injection agent into a space in a tissue of a patient. The tissue is less permeable to the injection agent than the space. The injection system also includes a support platform configured to support the injection assembly and anchor the injection assembly relative to a site of injection, a drive assembly configured to operate the injection assembly, one or more sensors configured to monitor one or more forces on the injection assembly, and a controller in communication with the one or more sensors to receive information about the one or more forces on the injection system. The controller is configured, based on the information, to operate the drive assembly to advance the puncture element through the tissue toward the space such that the injection agent remains in the injection chamber until the puncture element fluidly connects the injection chamber with the space.

[007] In some examples, the injection assembly further includes a first sealing element moveably disposed within the lumen distal to the second sealing element, wherein the first sealing element and the second sealing element form a seal with the lumen and define the injection chamber between them. The puncture element can be in fluid communication with the injection chamber to deliver the injection agent from the injection chamber into a space in a tissue of a

patient. When a force is applied on the second sealing element in a distal direction, in response to a first opposing force as the puncture element advances through the tissue, the first sealing element moves in the distal direction to advance the puncture element in the distal direction, without conveying the injection agent through the puncture element, and in response to a second opposing force when the injection chamber is fluidly connected to the space, the first sealing element remains stationary and the injection agent is conveyed from the injection chamber through the puncture element.

[008] In some examples, the drive assembly is linked to the second sealing element to apply the force on the second sealing element to translate the second element in the distal direction. In some examples, the drive assembly comprises a linear actuator linked the second sealing element to apply the force on the second sealing element to translate the second element in the distal direction. In some examples, the drive assembly comprises a first driver configured to translate the syringe barrel relative to the support platform and a second driver linked to the second sealing element to translate the second sealing element relative to the syringe barrel. The one or more sensors can comprise a first load cell configured to measure force on the syringe barrel, and the one or more sensors can comprise a second load cell configured to measure force on the second sealing element. In some examples, the one or more sensors comprise one or more of a pressure sensor, force sensor, strain sensor, position sensor or low rate sensor.

[009] In some examples, the controller is programmed to implement one or more feedback loops to monitor the first opposing force and the second opposing force. In some examples, the controller is programmed to implement one or more feedback loops to monitor a pre-insertion of the puncture element into the tissue, with the one or more feedback loops being configured to monitor an increase in force onto the puncture element, to detect a drop in force on the puncture element, and based on the drop, to cause an advancement of the puncture element by a pre-determined distance to imbed the puncture element into the tissue. In some examples, the controller is programmed to implement one or more feedback loops to monitor an advancement of the puncture element through the tissue, the one or more feedback loops being configured to measure a load on the second sealing element and detect a drop in the load once the puncture element reaches the space in the tissue. In some examples, the controller is programmed to implement one or more feedback loops to monitor an injection of the injection agent into the space, with the one or more feedback loops being configured to control a velocity or an advancement

distance of the second sealing element. In some examples, the controller is programmed to cause a retraction of the puncture element by a pre-determined distance when the one or more sensors detect a drop in load on the second sealing element. In some examples, the controller is programmed to control a stopping distance of the puncture element as the puncture element enters the space.

[0010] In some examples, the tissue is conjunctiva and the space is subconjunctival space. In some examples, the tissue is sclera and the space is suprachoroidal space. In some examples, the tissue is sclera and choroid and the space is intravitreal space. In some examples, the tissue is cornea and the space is an anterior chamber of an eye.

[0011] In some aspects, the present disclosure provides an injection system that comprises an injection assembly comprising a syringe barrel defining a lumen between a proximal end and a distal end, a first sealing element and a second sealing element moveably disposed within the lumen. The second sealing element is distal to the first sealing element to define an injection chamber. A puncture element is fluidly connected to the injection chamber and configured to deliver an injection agent from the injection chamber into a space in a tissue of a patient. The tissue is less permeable to the injection agent than the space. The injection system also includes a support platform configured to support the injection assembly and anchor the injection assembly relative to a site of injection, a drive assembly configured to translate one or both of the syringe barrel or the second sealing element relative to the support platform, one or more sensors configured to monitor one or more forces on the injection assembly, and a controller in communication with the one or more sensors to receive information about the one or more forces on the injection system. The controller in communication with the one or more sensors receives information about the one or more forces on the injection system, and is configured to, based on the information, to control the drive assembly to advance the puncture element through the tissue toward the space such that when the drive assembly translates the second sealing element in a distal direction. In response to a first opposing force as the puncture element advances through the tissue, the first sealing element moves in the distal direction to advance the puncture element in the distal direction, without conveying the injection agent through the puncture element, and in response to a second opposing force when the injection chamber is fluidly connected to the space, the first sealing element remains stationary and the injection agent is conveyed from the injection chamber through the puncture element.

[0012] In some examples, the drive assembly is configured to translate independently of one another the syringe barrel and the second sealing element relative to the support platform. In some examples, the drive assembly is linked to the second sealing element to apply the force on the second sealing element to translate the second element in the distal direction. In some examples, the drive assembly comprises a linear actuator linked the second sealing element to apply the force on the second sealing element to translate the second element in the distal direction. In some examples, the drive assembly comprises a first driver configured to translate the syringe barrel relative to the support platform and a second driver linked to the second sealing element to translate the second sealing element relative to the syringe barrel.

[0013] In some examples, the one or more sensors comprise a first load cell configured to measure force on the syringe barrel. In some examples, the one or more sensors comprise a second load cell configured to measure force on the second sealing element. In some examples, the one or more sensors comprise one or more of a pressure sensor, force sensor, strain sensor, position sensor or low rate sensor.

[0014] In some examples, the controller is programmed to implement one or more feedback loops to monitor the first opposing force and the second opposing force. In some examples, the controller is programmed to implement one or more feedback loops to monitor a pre-insertion of the puncture element into the tissue. The one or more feedback loops can be configured to monitor an increase in force onto the puncture element, to detect a drop in force on the puncture element, and based on the drop, to cause an advancement of the puncture member by a pre-determined distance to imbed the puncture element into the tissue. In some examples, the controller is programmed to implement one or more feedback loops to monitor an advancement of the puncture element through the tissue, with the one or more feedback loops being configured to measure a load on the second sealing element and detect a drop in the load once the puncture element reaches the space in the tissue. In some examples, the controller is programmed to implement one or more feedback loops to monitor an injection of the injection agent into the space, with the one or more feedback loops being configured to control a velocity or an advancement distance of the second sealing element. In some examples, the controller is programmed to cause a retraction of the puncture element by a pre-determined distance when the one or more sensors detect a drop in load on the second sealing element. In some examples, the controller

is programmed to control a stopping distance of the puncture element as the puncture element enters the space.

[0015] In some examples, the tissue is conjunctiva and the space is subconjunctival space. In some examples, the tissue is sclera and the space is suprachoroidal space. In some examples, the tissue is sclera and choroid and the space is intravitreal space. In some examples, the tissue is cornea and the space is an anterior chamber of an eye.

[0016] In an example, a method of delivering an injection agent is provided that comprises inserting a puncture element into a tissue. The puncture element can be configured to deliver an injection agent from an injection chamber into a space in the tissue, with the tissue having a density greater than the space such that the tissue is less permeable to the injection agent than the space. The method also includes advancing, using a drive assembly, the puncture element through the tissue toward the space, monitoring one or more forces on the puncture element using one or more sensors, and controlling, using a controller in communication with the one or more sensors, the drive assembly to advance the puncture element through the tissue toward the space such that the injection agent remains in the injection chamber until the puncture element fluidly connects the injection chamber with the space.

[0017] In some examples, the puncture element is positioned on a distal end of an injection assembly comprising a syringe barrel defining a lumen between a proximal end and a distal end and a first and second sealing element moveably disposed within the lumen to dispense the injection agent from the injection chamber. In some examples, in response to a first opposing force of the one or more force on the puncture element as it advances through the tissue, the first sealing element moves in a distal direction to advance the puncture element in the distal direction, without conveying the injection agent through the puncture element. In some examples, in response to a second opposing force of the one or more forces on the puncture element when the injection chamber is fluidly connected to the space, the first sealing element remains stationary and the second seal element moves in a distal direction such that the injection agent is conveyed from the injection chamber through the puncture element into the space.

[0018] In some examples, the tissue is conjunctiva and the space is subconjunctival space. In some examples, the tissue is sclera and the space is suprachoroidal space. In some examples, the tissue is sclera and choroid and the space is intravitreal space. In some examples, the tissue is cornea and the space is an anterior chamber of an eye.

[0019] In an example, a method of delivering an injection agent is provided that comprises positioning an injection assembly adjacent a tissue. The injection assembly comprises a syringe barrel defining a lumen between a proximal end and a distal end and a second sealing element moveably disposed within the lumen to dispense an injection agent from an injection chamber defined in the syringe barrel, and a puncture element extending configured to deliver the injection agent into a space in the tissue. The tissue has a density greater than the space such that the tissue is less permeable to the injection agent than the space. The method also includes monitoring one or more forces on the injection assembly using one or more sensors, and controlling the injection assembly using the forces on the injection system using a controller in communication with the one or more sensors to advance the puncture element through the tissue toward the space such that the injection agent remains in the injection chamber until the puncture element fluidly connects the injection chamber with the space.

[0020] In some examples, in response to a first opposing force of the one or more force on the puncture element as it advances through the tissue, the first sealing element moves in a distal direction to advance the puncture element in the distal direction, without conveying the injection agent through the puncture element. In some examples, in response to a second opposing force of the one or more forces on the puncture element when the injection chamber is fluidly connected to the space, the first sealing element remains stationary and the second seal element moves in a distal direction such that the injection agent is conveyed from the injection chamber through the puncture element into the space. In some examples, the method further comprises anchoring the injection assembly relative to a site of injection in the tissue.

[0021] In some examples, the tissue is conjunctiva and the space is subconjunctival space. In some examples, the tissue is sclera and the space is suprachoroidal space. In some examples, the tissue is sclera and choroid and the space is intravitreal space. In some examples, the tissue is cornea and the space is an anterior chamber of an eye.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The present disclosure is further described in the detailed description which follows, in reference to the noted plurality of drawings by way of non-limiting examples of exemplary embodiments, in which like reference numerals represent similar parts throughout the several views of the drawings, and wherein