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ADJUSTABLE FLOW GLAUCOMA SHUNTS AND METHODS FOR MAKING AND USING SAME

Abstract

Adjustable flow glaucoma shunts are disclosed herein. In one embodiment, for example, an adjustable flow shunt can include an outflow drainage tube having a proximal inflow region and a distal outflow region. The proximal inflow region can include aperture(s) defining a fluid inlet area positioned to allow fluid to flow therethrough. The shunt further comprises an inflow control assembly at the proximal inflow region. The inflow control assembly can include a control element configured to slidably engage the proximal inflow region and a spring element. The spring element is configured to be activated by non-invasive energy and, upon activation, slidably move the control element along the proximal inflow region such that (a) the one or more apertures are accessible and have a first fluid flow cross-section or (b) the one or more apertures are at least partially covered by the control element and have a second, different fluid-flow cross-section.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION(S) [0001] This application is a continuation of U.S. patent application Ser. No. 17/500,210, filed Oct. 13, 2021, which is a continuation of U.S. patent application Ser. No. 16/840,108, filed Apr. 3, 2020, now issued as U.S. Pat. No. 11,166,848, which is a continuation of U.S. patent application Ser. No. 16/632,008, filed Jan. 17, 2020, now issued as U.S. Pat. No. 11,058,581, which is a 35 U.S.C. § 371 U.S. National Phase application of International Patent Application No. PCT/US2018/043158, filed Jul. 20, 2018, which claims priority to U.S. Provisional Patent Application No. 62/643,125, filed Mar. 14, 2018, Provisional Patent Application No. 62/626,615, filed Feb. 5, 2018, and Provisional Patent Application No. 62/535,125, filed Jul. 20, 2017, the contents of which are all incorporated herein by reference in their entireties.

TECHNICAL FIELD
[0002] The present technology relates to adjustable flow glaucoma shunts and methods for making and using such devices.
BACKGROUND
[0003] Glaucoma, ocular hypertension, is a disease associated with an increase in pressure within the eye resultant from an increase in production of aqueous humor (aqueous) within the eye and/or a decrease in the rate of outflow of aqueous from within the eye into the blood stream. Aqueous is produced in the ciliary body at the boundary of the posterior and anterior chambers of the eye. It flows into the anterior chamber and eventually into the capillary bed in the sclera of the eye. Glaucoma typically results from a failure in mechanisms that transport aqueous out of the eye and into the blood stream.
[0004] Normal aqueous production, for example, is around 2.5 uL/min, and if it is assumed the lowest pressure that can exist in the capillary bed into which the aqueous drains is 0 torr, then maximum outflow resistance in a normal eye at the maximum of normal pressure is expected to be approximately 9 torr/(uL/min). Normal pressure within the eye ranges between 12 torr and 22 torr. As noted above, glaucoma is usually associated with high pressure inside the eye that can damage eye tissues and result in vision loss. The condition where pressures are significantly below this range is called hypotany or ocular hypotension. In some patients, hypotany can be just as damaging (if not more) than glaucoma.
[0005] The early stages of glaucoma are typically treated with drugs. When drug treatments no longer suffice, however, surgical approaches are used. Surgical or minimally invasive approaches primarily attempt to lower the outflow resistance of aqueous from the anterior chamber to the blood

stream either by the creation of alternative fluid paths or the augmentation of the natural paths for aqueous outflow.

[0006] Devices used to lower outflow resistance are generally referred to as “glaucoma shunts” or “shunts.” FIGS. **1**A-**1**C, for example, illustrate several different traditional glaucoma plate shunts **100** (identified individually as **100***a-c*) configured to provide constant resistance to flow. The shunt **100***a* of FIG. **1**A, for example, includes a plate **103***a*, a plurality of outflow ports **102***a*, one or more inflow ports **101**, and tie-downs or engagement features **104***a*. The shunts **100***b* and **100***c* shown in FIGS. **1**B and **1**C, respectively, include several features similar to the features of shunt **100***a*. For example, these shunts **100***b-c* include plates **103***b-c*, outflow ports **102***b-c*, and tie-downs or engagement features **104***b-c*. The shunts **100***b-c*, however, include an inflow tube **105** instead of the inflow ports **101** of the shunt **100***a*.

[0007] FIGS. **2**A and **2**B illustrate a human eye E and suitable location(s) in which shunts **100***a-c* may be implanted within the eye. More specifically, FIG. **2**A is a simplified front view of the eye E, and FIG. **2**B is an isometric view of the eye capsule of FIG. **2**A. Referring first to FIG. **2**A, the eye E includes a number of muscles to control its movement, including a superior rectus SR, inferior rectus IR, lateral rectus LR, medial rectus MR, superior oblique SO, and inferior oblique IO. The eye E also includes an iris, pupil, and limbus.

[0008] Referring to FIGS. **2**A and **2**B together, shunt **100***c* is positioned such that inflow tube **105** is positioned in an anterior chamber of the eye, and outflow ports **102***c* are positioned at a different location within the eye. Depending upon the design of the device, the outflow ports **102***c* may be place in a number of different suitable outflow locations (e.g., between the choroid and the sclera, between the conjunctiva and the sclera). For purposes of illustration, only shunt **100***c* is shown implanted in the eye E. It will be appreciated, however, that shunts **100***a-b* may be similarly implanted within the eye E.

[0009] Outflow resistance typically depends on the outflow location. Additionally, outflow resistance changes over time as the outflow location goes through its healing process after surgical implantation of the device. Because the outflow resistance changes over time, in many procedures the shunt **100***a-c* is modified at implantation to temporarily increase its outflow resistance. After a period of time deemed sufficient to allow for healing of the tissues and stabilization of the outflow resistance, the modification to the shunt **100***a-c* is reversed, thereby decreasing the outflow resistance. Such modifications can be invasive, time-consuming, and expensive for patients. If such a procedure is not followed, however, the likelihood of creating hypotany and its resultant problems is high.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily drawn to scale. Instead, emphasis is placed on illustrating clearly the principles of the present technology. Furthermore, components can be shown as transparent in certain views for clarity of illustration only and not to indicate that the component is necessarily transparent. Components may also be shown schematically.

[0011] FIGS. **1**A-**1**C illustrate traditional glaucoma plate shunts configured to provide constant resistance to flow.

[0012] FIG. **2**A is simplified front view of an eye E with an implanted shunt, and FIG. **2**B is an isometric view of the eye capsule of FIG. **2**A.

[0013] FIGS. **3**A and **3**B illustrate an adjustable flow glaucoma shunt configured in accordance with an embodiment of the present technology.

[0014] FIG. **3**C is a partially schematic illustration of an eye capsule of a human patient showing the adjustable flow glaucoma shunt of FIGS. **3**A and **3**B implanted within the eye capsule.
[0015] FIGS. **3**D and **3**E illustrate inflow regions configured in accordance with additional embodiments of the present technology.
[0016] FIGS. **4**A-**4**C illustrate an adjustable flow glaucoma shunt configured in accordance with another embodiment of the present technology.
[0017] FIGS. **5**A-**6**B illustrate inflow control assemblies configured in accordance with embodiments of the present technology.
[0018] FIGS. **7**A-**7**E illustrate a variable flow shunt configured in accordance with an embodiment of the present technology.
[0019] FIGS. **8**A-**9**B illustrate additional embodiments of variable flow glaucoma shunt devices configured in accordance with the present technology.
[0020] FIG. **10** illustrates a variable flow shunt device including an actuatable member at an outflow end of the device in accordance with an embodiment of the present technology.
[0021] FIGS. **11**A-**11**C illustrate a ribbon or wire composed of shape memory material and configured in accordance with an embodiment of the present technology.
[0022] FIGS. **12**A and **12**B illustrate a fluid control element including variable fluid resistors composed of shape memory materials in accordance with an embodiment of the present technology.
[0023] FIGS. **13**A and **13**B are partially schematic, cross-sectional views of a variable fluid resistor comprising a dual lumen elastomeric tube configured in accordance with an embodiment of the present technology.
[0024] FIGS. **13**C-**13**F illustrate additional embodiments of variable fluid resistor devices configured in accordance with the present technology.
[0025] FIGS. **14**A and **14**B illustrate a fluid control element including variable fluid resistors composed of shape memory materials in accordance with additional embodiments of the present technology.
[0026] FIGS. **15**A-**15**C illustrate an adjustable flow glaucoma shunt configured in accordance with another embodiment of the present technology.
[0027] FIGS. **16**A-**16**E illustrate an adjustable flow glaucoma shunt configured in accordance with still another embodiment of the present technology.

DETAILED DESCRIPTION

[0028] The present technology is directed to adjustable flow glaucoma shunts and methods for making and using such devices. In many of the embodiments disclosed herein, the adjustable flow glaucoma shunts comprise an adjustable fluid resistor (“resistor” within the context of this document refers to a fluid resistor), actuator, and/or actuation mechanism. Additionally, in certain embodiments, the shunts may also include an adjustable opening pressure control mechanism. These mechanisms can be selectively adjusted or modulated to increase or decrease the outflow resistance and/or opening pressure of the shunt in response to changes in any (or any combination of) intraocular pressure (IOP), aqueous production rate, native aqueous outflow resistance, and/or native aqueous outflow rate.
[0029] In one embodiment, for example, an adjustable flow shunt for treating glaucoma in a human patient comprises an elongated outflow drainage tube having a proximal inflow region and a distal outflow region. The proximal inflow region can include one or more apertures defining a fluid inlet area positioned to allow fluid to flow therethrough and into the outflow drainage tube. The adjustable flow shunt further comprises an inflow control assembly at the proximal inflow region. The inflow control assembly can include a control element sized and shaped to slidably engage the proximal inflow region and a spring element operably coupled between the control element and an anchor element engaged with the proximal inflow region. The spring element is configured to be activated by a non-invasive energy and, upon activation, slidably move the control element along

the proximal inflow region such that (a) the one or more apertures are accessible and have a first fluid flow cross-section or (b) the one or more apertures are at least partially covered by the control element and have a second fluid-flow cross-section less than the first fluid flow cross-section.

[0030] In another embodiment of the present technology, an adjustable flow shunt for treatment of glaucoma may comprise an elongated outflow tube having (a) a proximal inflow portion configured for placement within an anterior chamber in a region outside of an optical field of view of an eye of the patient, and (b) a distal outflow portion at a different location of the eye. The adjustable flow shunt also includes an actuator positioned along the outflow tube between the inflow portion and the outflow portion. The actuator is transformable between an open position that allows fluid to flow through the outflow tube and resistance positions that partially obstruct fluid flow through the outflow tube. During operation, the actuator is movable between positions in response to non-invasive energy.

[0031] An adjustable flow shunt assembly configured in accordance with still another embodiment of the present technology can include an elongated drainage tube having a proximal portion and a distal portion. The proximal portion includes an inflow port configured to be in fluid communication with a fluid chamber in an eye of the patient. The adjustable flow shunt can also include a variable resistor assembly configured to selectively control flow of fluid into the inflow port. The variable resistor assembly in this embodiment comprises a base portion and an aperture plate carried by the base portion. The aperture plate comprises a plurality of first apertures extending therethrough. The variable resistor assembly also comprises a standoff plate carried by and extending away from the aperture plate. The standoff plate comprises a plurality of second apertures extending therethrough, with the second apertures aligned with corresponding first apertures of the aperture plate. The variable resistor assembly further comprises a membrane disposed on and carried by the standoff plate. The membrane is positioned to sealably cover an open end of each of the second apertures. During operation of the shunt assembly, a portion of the membrane over one or more second apertures of the standoff plate is configured to be selectively targeted and removed via non-invasive energy, thereby creating a fluid path from the site of fluid in the patient through the accessible open ends of the targeted second apertures, the corresponding first apertures, and into the drainage tube.

[0032] Specific details of various embodiments of the present technology are described below with reference to FIGS. **3**A-**16**E. Although many of the embodiments are described below with respect to adjustable flow glaucoma shunts and associated methods, other embodiments are within the scope of the present technology. Additionally, other embodiments of the present technology can have different configurations, components, and/or procedures than those described herein. For instance, shunts configured in accordance with the present technology may include additional elements and features beyond those described herein, or other embodiments may not include several of the elements and features shown and described herein.

[0033] For ease of reference. throughout this disclosure identical reference numbers are used to identify similar or analogous components or features, but the use of the same reference number does not imply that the parts should be construed to be identical. Indeed, in many examples described herein, the identically numbered parts are distinct in structure and/or function.

Selected Embodiments of Variable Flow Glaucoma Shunts

[0034] FIGS. **3**A-**16**E illustrate a number of different embodiments for variable flow glaucoma shunt devices, along with particular components and features associated with such devices. FIG. **3**A, for example, illustrates a variable flow glaucoma shunt **300** (“shunt **300**”) configured in accordance with an embodiment of the present technology. The shunt **300** includes an inflow control assembly **338** and an outflow drainage tube or outflow assembly **327**. The inflow control assembly **338** of the shunt **300** is configured for placement within an anterior chamber in a region outside of the optical field of view of the eye, but within a region visible through the cornea (as described below with reference to FIG. **3**C). The outflow drainage tube **327** comprises tubing (e.g.,

a fine bore length of thin walled tubing) sized and shaped to span the region between the anterior chamber and a desired outflow location. As described in greater detail below, the inflow control assembly **338** comprises a control mechanism configured to act as a variable resistor during operation.

[0035] FIG. **3**B is a partially exploded view of the shunt **300** with a portion of the inflow control assembly **338** removed from the outflow drainage tube **327** for purposes of illustration. As best seen in FIG. **3**B, a proximal end **360** of the outflow drainage tube **327** comprises a proximal inflow region defined by a core element or core feature **342** extending therefrom. The core element **342** may be composed of a relatively stiff material or a combination of stiff materials including, but not limited to, polyether ether ketone (PEEK), acrylic, polycarbonate, metal, ceramic, quartz, and/or sapphire. The portion of the outflow drainage tube **327** not comprised in the core element **342** may be composed of a relatively flexible material (e.g., silicone, urethane, or another suitable material). The core element **342** includes one or more apertures or openings **341** (only one is shown in the illustrated embodiment) that define a fluid inlet area **362**. The fluid inlet area **362** is in fluid communication with a lumen of the outflow drainage tube **327**. In other embodiments, the aperture(s) **341** may have a different arrangement and/or there may be a different number of apertures **341**. For example, in another embodiment the aperture **341** may extend helically about the core element **342**. The aperture(s) **341** are positioned to allow fluid to flow therethrough during operation of the shunt **300**.

[0036] Referring to FIGS. **3**A and **3**B together, for example, the inflow control assembly **338** in the illustrated embodiment includes a control element **339** configured to be positioned on or around an external surface of the core element **342** (as shown by the arrow in FIG. **3**B). During operation, the control element **339** may be adjusted to cover more or less of the fluid inlet area **362**. For example, in some embodiments, the control element **339** may be adjusted to increase or decrease the length of a fluid path between an edge of the control section **339** and the aperture(s) **341** (FIG. **3**B). In some embodiments, a hydrogel coating may be applied to an inside surface of the control element **339** to further enhance the ability of the control element **339** to slide relative to the core element **342** and enhance sealing of the components during operation. In additional embodiments, the hydrogel coating may also be applied to the core element **342** (in addition to, or in lieu of, application of the coating on the control element **339**). Further details regarding adjusting/manipulating the control element **339** are described below.

[0037] The inflow control assembly **338** in the illustrated embodiment can also include an adjustable spring element (shown as first and second spring elements **340** and **340**′) arranged on opposite sides of the control element **339**. Each spring element **340** and **340**′ may further comprise a corresponding anchor element **310**.

[0038] In the embodiment illustrated in FIGS. **3**A and **3**B, the control element **339** is composed of a single material. For example, the control element **339** may be fabricated from materials such as (but not limited to) ceramics, alumina oxide, silica oxide, sapphire, and/or quartz. Such materials, for example, may be ground to very high tolerances/precise dimensions. In other embodiments, however, the control element **339** may have different portions/regions composed of different materials. The first and second spring elements **340** and **340**′ may be composed of a shape memory material (e.g., nitinol or another suitable shape memory material) capable of activation via non-invasive energy, such as light (and or heat). The anchor elements **310** may be fabricated from similar material(s) or other suitable materials.

[0039] In operation, first and second spring elements **340** and **340**′ are configured to be selectivity activated by non-invasive energy and, upon activation, slidably move the control element **339** along the proximal inflow region in a first direction or a second direction, respectively, such that (a) the aperture(s) **341** have a first fluid flow cross-section (e.g., completely open and accessible), or (b) the aperture(s) are at least partially covered by the control element **339** and have a second fluid-flow cross-section less than the first fluid flow cross-section (e.g., partially open/accessible).

Further, in some instances the control element **339** may be slidably adjusted such that the aperture(s) **341** are fully covered and inaccessible. One feature of the arrangement shown in FIGS. **3**A and **3**B is that the inflow control assembly **338** can be selectively adjusted after placement within the eye (e.g., via non-invasive energy) to provide a variety of different outflow resistance levels by incrementally adjusting the control element **339** relative to the aperture(s) **441**.

[0040] FIG. **3**C is a partially schematic illustration of an eye capsule of a human patient showing the adjustable flow glaucoma shunt **300** of FIGS. **3**A and **3**B implanted within the eye capsule. In particular, a typical surgery for implantation of the shunt **100** in the eye capsule comprises the following: (a) a portion of conjunctiva is peeled back; (b) a portion of sclera is removed to create a pocket where the plate is to be placed; (c) the inflow control assembly **338** is routed into the anterior chamber of the eye capsule; (d) the outflow drainage tube **327** is extended through the tissue and into a desired pocket; and (c) the outflow drainage tube **327** and any other portions of the shunt **300** not otherwise buried in the other tissues are covered with conjunctiva. In the embodiment illustrated in FIG. **3**C, for example, the shunt **300** is configured for placement traversing a region in the anterior chamber to a region in a suprachoroidal location of the eye. In other embodiments, however, the shunt **300** may be adapted for placement within different portions of the eye. In one embodiment, for example, shunts configured in accordance with the present technology may be positioned at a subconjunctival region within the eye.

[0041] FIGS. **3**D and **3**E illustrate core elements configured in accordance with different embodiments of the present technology. Referring first to FIG. **3**D, for example, core element **342** comprises a plurality of apertures or openings **341′** extending therethrough and defining, at least in part, a fluid path in communication with a lumen of the corresponding outflow drainage tube **327**. The apertures **341′** in the illustrated embodiment have a different arrangement/configuration than the aperture **341** described above with reference to FIGS. **3**A and **3**B. It will be appreciated that while six apertures **341′** are shown in FIG. **3**D, the core element **342** may include a different number of apertures **341′** in other embodiments. Moreover, the apertures **341′** may have a different arrangement relative to each other. FIG. **3**E illustrates yet another embodiment of core element **342** having apertures **341″** configured in accordance with still yet another arrangement of the present technology. In this embodiment, the apertures **341″** comprise a plurality of elongated slots arranged about the core element **342**. In other embodiments, the apertures **341′**/**341″** may have a variety of other suitable shapes/sizes.

[0042] FIGS. **4**A-**4**C illustrate a variable flow glaucoma shunt **400** ("shunt **400**") configured in accordance with yet another embodiment of the present technology. The shunt **400** includes an inflow control assembly **438** and an outflow drainage tube or outflow assembly **427**. The inflow control assembly **438** includes several features similar to the inflow control assembly **338** of the shunt **300** described above with reference to FIGS. **3**A and **3**B. For example, inflow control assembly **438** includes a first or proximal spring element **440′** and a second or distal spring element **440** arranged adjacent each other. The inflow control assembly **438** further includes a core element or feature **442** coupled to an inner portion of the inflow control assembly at anchor point **442′** (as best seen in FIGS. **4**B and **4**C) between the spring elements **440** and **440′**. A fixation spine **451** extends between and is operably coupled to the spring elements **440** and **440′**. Although only one fixation spine **451** is shown in the illustrated embodiment, in other embodiments the shunt **400** may include one or more additional fixation spines. In the illustrated embodiment, the fixation spine **451** and first and second spring elements **440** and **440′** are all integrally formed from the same tube using a laser cutting process. In other embodiments, however, the spring elements **440** and **440′** and/or fixation spine **451** may be separate, discrete components formed from different materials.

[0043] In operation, the shunt **400** is configured to operate in an analogous fashion to the shunt **300** described above with respect to FIGS. **3**A-**3**C. In particular, the first and second spring elements **440** and **440′** are configured to be selectivity activated by non-invasive energy and, upon activation, slidably move the core element **442** to change the length of a flow path through openings or slits

460 of the inflow control assembly **438**. Referring to FIG. **4**B, for example, when the distal spring **440** is expanded/actuated, the core element **442** moves proximally and the length of the core portion **442** inside an uncut portion of the shunt **400** (and the corresponding flow F through openings **460** and along flow path FP in the inflow control assembly **438**) is at a minimum.
[0044] Referring to FIG. **4**C, however, when the distal spring **440** is compressed and the proximal spring **440′** is expanded/actuated, the length of the core portion **442** inside the uncut portion (and the corresponding flow F along flow path FP) is maximized. The disclosed arrangement is expected to provide an effective and predictable way to incrementally increase/decrease flow resistance in a linear fashion via the shunt **400**. In other embodiments, rather than the incremental adjustments in flow rate provided by the shunt **400** shown in FIGS. **4**A-**4**C, the shunt **400** may be configured to provide a binary on/off arrangement via selective actuation of the first and second spring elements **440** and **440′**. Further, in some embodiments, the width and/or shape of the openings/slits **460** can be modified to allow for further control of the flow resistance of the shunt **400**. In yet another embodiment the core pin may be affixed to the proximal end of spring element **440′** and not extend into a flow path. In such an embodiment, the flow path is altered by expanding or compressing the space between the elements of the spring **440** and **440′**. In other embodiments, the shape of the pin and or the inner lumen can be modified to change allow for a nonlinear control of flow as a function of core travel.
[0045] FIGS. **5**A-**6**B illustrate inflow control assemblies configured in accordance with further embodiments of the present technology. Referring first to FIGS. **5**A and **5**B, for example, inflow control assembly **538** is positioned on or around an external surface of core element **542** at the inflow or inlet region of the drainage tube **527**. Inflow control assembly **538** comprises control element **539** and spring elements **540** fixed thereto and extending in a proximal direction toward the drainage tube **527**. The inflow control assembly **538** further includes an anchor element **510** operably coupled to the spring elements **540** at a proximal region of the inflow control assembly **538**. FIG. **5**A illustrates the inflow control assembly **538** in a low or minimum flow configuration in which control element **539** is positioned entirely over or approximately entirely over apertures **541** (FIG. **5**B) in the core element **542**. FIG. **5**B illustrates the inflow control assembly **538** in a maximum flow configuration in which the spring elements **540** have been actuated. In some embodiments, for example, the spring element **540** may be heated via non-invasive energy (e.g., laser energy), thereby causing the spring elements **540** to bow outwardly and slidably move control element **539** in a proximal direction such that apertures **541** are exposed and fluid can flow therethrough into drainage tube **527**.
[0046] FIGS. **6**A and **6**B illustrate another embodiment of an inflow control assembly **638** configured in accordance with the present technology. In this embodiment, the inflow control assembly **638** includes a control element **639** and first and second spring elements **640** and **640′** fixed thereto and extending in a proximal direction toward the drainage tube **627**. The first and second spring elements **640** and **640′** have a different configuration than spring elements **540** and **540′** described above with reference to FIGS. **5**A and **5**B. Further, each spring element **640** and **640′** is operably coupled to a corresponding anchor element **610** and **610′**. Because the individual spring elements **640** and **640′** have their own anchor elements **610** and **610′**, respectively, the spring elements **640** and **640′** can be independently set in an initial configuration and independently controlled during operation. As shown in FIG. **6**B, for example, the individual spring elements **640** and **640′** can be actuated (e.g., via heat), thereby causing the spring elements **640** and **640′** to coil more tightly and slidably move control element **639** in a proximal direction along core element **642** and create an open fluid path (to a lumen of drainage tube **627**) via exposed apertures **641**.
[0047] In the embodiments shown in in FIGS. **3**A-**6**B, the inflow ends of the various illustrated shunts are sealed. Such shunts may be delivered via a needle (not shown) traversing a desired flow path (as described above with reference to FIG. **3**C). In other embodiments, however, the inflow end of a shunt may be initially open (such that the shunt can be delivered over a guide wire) and

then sealed after delivery and placement.

Additional Embodiments of Adjustable Flow Glaucoma Shunts

[0048] A collection of additional embodiments of adjustable flow and/or adjustable pressure regulated glaucoma shunts comprising plates are described below with reference to FIGS. **7**A-**16**E. Such shunts may be implanted as described above and illustrated in FIG. **3**C, or the shunt(s) may be implanted using other suitable techniques and in other suitable locations within the eye. In some of these embodiments, traditional outflow ports are augmented with additional tubes to distribute the aqueous over larger regions of tissue. Outflow tube(s) are covered by at least the conjunctiva. Many of the embodiments of the present technology additionally comprise an adjustable fluid resistor, some of which may additionally comprise an adjustable opening pressure control mechanism. These mechanisms can be adjusted to increase or decrease the outflow resistance and/or opening pressure of the shunt in response to changes in the following: IOP, aqueous production rate, native aqueous outflow resistance, native aqueous outflow rate, and combinations thereof.

[0049] FIGS. **7**A-**7**E illustrate another embodiment of a variable flow shunt **700** configured in accordance with the present technology. FIG. **7**A, for example, is a schematic top view of the shunt **700**, which is configured for minimally invasive placement (like the shunts described above with reference to FIGS. **3**A-**6**B). The shunt **700** includes an elongated drainage tube **702** having a proximal portion with an inflow port **701** and a distal portion opposite the proximal portion. The shunt **700** differs from the shunts describe above in that fluid resistance of the shunt **700** is selectively controlled by modifying the number of apertures that allow fluid to flow through the inflow port **701**. In some embodiments, for example, the shunt **700** can be configured to allow only for sequential decreases in outflow resistance. In other embodiments, however, the shunt **700** may be configured to selectively allow for both finite decreases and increases in outflow resistance. Further details regarding the shunt **700** and its operation are described below.

[0050] FIG. **7**B is an enlarged, partially schematic cross-sectional view of the shunt **700** taken along line B-B of FIG. **7**A, and FIG. **7**C is an enlarged view of the region C identified in FIG. **7**B. Referring to FIGS. **7**B and **7**C together, the inflow port **701** of the shunt **700** further comprises a variable resistor assembly **720** configured to selectively control flow of fluid into the inflow port (and the outflow port **702**). The variable resistor assembly **720** comprises a membrane **745** disposed on and carried by a standoff plate **746**. The standoff plate **746** is operably coupled to and extends from aperture plate **747**. The aperture plate **747** is carried by a base portion or housing **748** of the shunt **700**.

[0051] The aperture plate **747** comprises a plurality of first apertures or first openings **760** extending therethrough. The first apertures **760** have a first cross-sectional dimension D.sub.1 (not shown). The first apertures **760** can be precisely formed so that each opening is identical or nearly identical and all of the first apertures **760** are a predetermined size. The standoff plate **746** comprises a plurality of second apertures or second openings **741** extending therethrough. The second apertures **741** have a second cross-sectional dimension D.sub.2 larger than the first cross-sectional dimension D.sub.1. As will be described in greater detail below, the second apertures **741** do not need to be as precisely formed as the first apertures **760**. As shown in FIG. **7**C, the membrane **745** completely covers one end (an upper or first end) of each of the second apertures **741**. The opposite end of each second aperture **741** (a second or lower end) is aligned with a corresponding first aperture or first opening **760** extending through the aperture plate **747**.

[0052] FIG. **7**D is a top view of the variable resistor assembly **720**. As best seen in FIG. **7**D, the variable resistor assembly **720** further comprises a plurality of target indicia or markers **713** ("targets **713**"). The individual targets **713** correspond to and are aligned with each first aperture **741** (FIG. **7**B). Referring next to FIG. **7**E, after the shunt **700** is implanted within a patient and it is desired to reduce the fluid resistance of the shunt **700**, non-invasive energy (e.g., a surgical laser) can directed at a selected target **713** on membrane **745**. In embodiments using laser energy, for

example, the laser can be activated or fired to selectively ablate the targeted material of the membrane **745**, thereby removing such membrane material and exposing the open end of the corresponding second aperture **741**. Without the membrane blocking the targeted second aperture **741**, fluid can flow therethrough (as shown by the arrow F), and subsequently through the corresponding first aperture **760** and into the outflow drainage tube **702**. If a further reduction in fluid resistance is desired, one or more additional targets **713** on membrane **745** may be ablated to expose additional second apertures **741** and allow additional fluid to flow therethrough to outflow drainage tube **702**.

[0053] In the illustrated embodiment, outflow resistance can only be lowered as there is no means of sealing the second apertures **741** of the implanted shunt **700** once the corresponding targeted portions of the membrane **745** are removed to open the second aperture(s) **741** to aqueous flow. In other embodiments, however, there may be techniques to later impede or stop fluid flow by blocking one or more open second apertures **741**. For example, referring to FIGS. **7**B and **7**C, in some embodiments the membrane **745** and standoff plate **746** may be composed, at least in part, from a hydrophobic material (e.g., a low melting point wax) adapted to be melted by the surgical laser (not shown) at temperatures that will not cause particular harm to the aqueous. In such embodiments, a relatively small, fine beam from the laser source can be used to melt the wax material of the target membrane **754** and open the corresponding second aperture **741**. At a later point in time, if it is desired to slow or limit flow of aqueous, a larger beam from the laser source can be used to melt the wax material of the standoff plate **746**, thereby causing the material to "puddle" or accumulate over the corresponding second aperture **760** within the previously opened second aperture **741** and close or block fluid flow through the first aperture **760**.

[0054] In the embodiment illustrated in FIGS. **7**A-**7**E, the components of the variable resistor assembly **720** are separate, discrete components that are operably coupled together before implantation of the shunt **700**. The components may be composed of similar materials, or one or more different materials. In other embodiments, however, the membrane **745** and standoff plate **746** may be fabricated as a single unitary component composed of the same material, such as the example described above in which the membrane **745** and standoff plate **746** comprise a unitary component composed of a hydrophobic material. In other embodiments, however, the integral membrane **745**/standoff plate **746** may be composed of other suitable materials. In still other embodiments, the standoff plate **746** and aperture plate **747** may be fabricated of a single unitary component composed of the same material with the first and second apertures **741** and **760** formed therein. In yet additional embodiments, the aperture plate **747** may be integrally formed with the base portion **748** of the shunt **700**.

[0055] FIGS. **8**A-**9**B illustrate additional embodiments of variable flow glaucoma shunt devices configured in accordance with the present technology. In these embodiments, the shunts are configured to be delivered to a target location within an eye capsule of the patient via a guidewire, and then transformed between a delivery configuration and a deployed configuration upon removal of the guidewire. FIG. **8**A, for example, illustrates shunt **800** in a delivery configuration on guidewire W. The shunt **800** includes an inflow control assembly **838** and an outflow tube or outflow assembly **827**. The inflow control assembly **838** can include several features generally similar to the shunts described above with reference to FIGS. **3**A-**6**B. For example, the shunt **800** includes a control element **839** positioned over one or more apertures or openings **841** (shown in broken lines) extending through a body portion **848** of the inflow control assembly **838**. The aperture(s) **841**, when at least partially exposed, are configured to allow aqueous to flow therethrough and into the outflow tube **827**. The shunt **800** also comprises a pair of adjustable spring elements **840** and **840′** arranged on opposite sides of the control element **839**. The spring elements **840** and **840′** are coupled between the body portion **848** and the control element **839**. In some embodiments, the spring elements **840** and **840′** are composed of a shape memory material (e.g., nitinol) and adapted to expand/contract when heat is applied. For example, applying heat to

the first spring element **840** can induce this spring element to coil more tightly, thereby moving the control element **839** toward the first spring element **840** and stretching or expanding the second spring element **840′**. Moving the control element **839** also at least partially exposes the aperture(s) **841** to allow aqueous to flow therethrough similar to the techniques described above with reference to FIGS. **3**A-**6**B.

[0056] In the illustrated embodiment, the inflow control assembly **838** is composed of a first material having a first rigidity and the outflow tube **827** is composed of a second material having a second rigidity less than the first rigidity. Referring to FIGS. **8**A and **8**B together, the shunt **800** may be preshaped prior to implantation such that the shunt **800** includes one or more bends along its length. In the illustrated embodiment, for example, the shunt **800** comprises a generally "L" shaped arrangement and includes a bend or elbow **854** at or near a distal region of the outflow tube **827**.

[0057] When the shunt **800** is positioned on guidewire W for delivery, the shunt **800** assumes a generally linear, straight delivery configuration. As shown in FIG. **8**B, however, when the guidewire W is removed, the shunt **800** transforms between its delivery configuration and an expanded/deployed configuration in which the shunt **800** assumes its predetermined "L" shaped arrangement including elbow **865**. This configuration is expected to allow for rapid and reliable delivery of the shunt **800** via guidewire W, and enable precise placement of the inflow control assembly **838** within the eye capsule of the patient once the guidewire is removed and the shunt **800** assumes is predetermined shape.

[0058] FIGS. **9**A and **9**B illustrate a shunt **900** configured in accordance with still another embodiment of the present technology. The shunt **900** includes a number of features generally similar to the features of shunt **800**. The shunt **900** differs from shunt **800** in that the shunt **900** is not composed of different materials having different rigidities. Rather, the shunt **900** comprises an inflow portion or region **938** and an outflow portion or outflow tube **927** composed of a single material (e.g., a shape memory material such as nitinol). The shunt **900**, like shunt **800** described above, also includes a preset, generally "L" shaped arrangement and includes a bend or elbow **954**. In this embodiment, however, removing the guidewire W does not transform the shunt **900** between its delivery configuration (FIG. **9**A) and its deployed/expanded configuration (FIG. **9**B). Instead, as best seen in FIG. **9**B, once guidewire W is removed and the shunt **900** is at a desired location within the patient, a laser source (e.g., an ophthalmic laser—not shown) can be used to direct a laser beam to selectively heat a portion of the shunt **900** and induce the shunt **900** to bend about elbow **954** and return to its preset shape (the generally "L" shaped arrangement).

[0059] FIG. **10** illustrates a variable flow shunt device **1000** configured in accordance with yet another embodiment of the present technology. The shunt **1000** comprises an inflow assembly **1001** and an outflow drainage tube **1027** with an outflow port **1002**. The shunt **1000** further comprises an actuatable member **1049** at the outflow end of the outflow port **1002** (opposite the inflow assembly **1001**). The actuatable member **1049** comprises one or more tissue disruption members **1050** (e.g., barbs or other suitable types of devices) to disrupt/disturb tissue at or proximate the outflow end of the outflow port **1001** after the shunt **1000** is implanted within the patient. In one embodiment, the barbs **1050** of the actuatable member **1049** can be moved and actuated by an operator via an externally applied magnetic field to disrupt target tissue adjacent the outflow end of the shunt **1000**. In other embodiments, however, the barbs **1050** may be moved/actuated using other suitable techniques, such as thermally induced shape changes. Further, it will be appreciated that a different number of barbs **1050** may be used and/or the barbs **1050** may have a different arrangement relative to each other and the actuatable member **1049**.

[0060] Many of the embodiments disclosed herein make use of a shape memory material (SMM), such as nitinol, shape memory polymers, and the like, as a control in an adjustable fluid resistor. As noted previously, such fluid resistors allow controlled flow of aqueous from within the anterior chamber of the eye to a location into which the aqueous can defuse. One such location is within or

on top of the sclera posterior to the cornea. In general, SMM elements utilized in the various devices disclosed herein can be repeatedly activated in one direction to increase fluid resistance and in another direction to decrease fluid resistance. In some embodiments, for example, each of multiple activations on targets in one section of the actuation element will incrementally increase the resistance, while multiple activations on targets in another section of the actuation element will incrementally decrease the resistance. When a target is heated above its transition temperature, such as by heating via non-invasive laser energy, the SMM shifts from its larger volume, lower stiffness, low temperature martensite (Mar) form to its high temperature, smaller volume, stiffer austenite form (Aus).

TABLE-US-00001 Aus (austenite) 75-83 GPa, smaller volume, high temperature Mar (martensite) 28-40 GPa, larger volume, low temperature

[0061] One such configuration is illustrated in FIGS. **11**A-**11**C, which represents a side view of a ribbon or wire configured in accordance with embodiments of the present technology. Referring first to FIG. **11**A, the ribbon has been shape-set in a form comprising multiple uniform folds. As illustrated, there are six folds, but it will be appreciated that in other embodiments ribbons with more or less folds can be used depending on the desired amount of resolution and displacement. Referring next to FIG. **11**B, the ribbon can then be mounted between two anchors such that the constrained length is larger than the heat set length. Referring now to FIG. **11**C, applying heat to the fold(s) in the portion of SMM heated above its Aus, shifts it from its less stiff, higher volume Mar form to its stiffer and lower volume Aus form. In the illustrated embodiment, the entire SMM component is not allowed to return to its heat set shape even if the entire portion of SMM is heated above the transformation temperature. The unheated portion can expand further to compensate. In addition, heating previously unheated sections is expected to stretch previously unheated and heated sections reversing the mechanism.

[0062] FIGS. **12**A and **12**B illustrate a fluid control element **1201** configured in accordance with another embodiment of the present disclosure. The fluid control element **1201** may be used with any of the variable flow shunts described herein or other suitable shunts. In this embodiment, the fluid control element **1201** comprises variable fluid resistors actuated by SMM elements (like those described above with reference to FIGS. **11**A-**11**C). Referring first to FIG. **12**A, fluid control element **1201** comprises a base **1211** and a flow-through drainage tube **1212** carried by and operably coupled to the base **121**. For example, the flow-through tube **1212** can be fixed to the base **1211** via flow-through anchors **1209**. In other embodiments, however, other suitable techniques may be used to secure the flow-through tube **1212** to the base **1211**. The flow-through tube **1212** is also operably engaged with an actuator **1218**. In the illustrated embodiment, the actuator **1218** comprises a ribbon or wire composed of SMM and including a plurality of folds. The actuator **1218** has a fixed length and each end of the actuator **1218** is anchored to the base **1211**.

[0063] The actuator **1218** may be actuated using techniques similar to those described above with reference to FIGS. **11**A-**11**C. During operation, for example, the tops of the folds along the actuator **518** may be used as target regions to be selectively heated via non-invasive energy (e.g., laser energy) to locally heat such regions along the actuator **518**. As discussed previously with respect to FIGS. **11**A-**11**C, heating folds on one side relative to the other side will allow incremental shifting of resistance (up or down) to modify the state of the actuator **1218**, and thereby change fluid resistance through the flow-through tube **1212**. FIG. **12**A, for example, illustrates a low-resistance state of the fluid control element **1201** in which the actuator **1218** is fairly uniform along its length and provides minimal resistance or interference with fluid flow through the flow-through tube **1212**. FIG. **12**B illustrates a high resistance state of the of the fluid control element **1201**. The high resistance state or high resistance position is a result, for example, of multiple actuations via the actuation element **1218** to the flow-through tube **1212**. In particular, heating each of the folds of the actuation element **1218** on the left side of the flow-through tube **1212** above the actuation temperature causes the actuation element **1218** in this region to shrink, thereby “pinching” and

compressing the flow-through tube **1212** in this direction and increasing fluid resistance therethrough. When desired, fluid control element **1201** can be transformed again to additional resistance positions or orientations than that shown in FIG. **12**B (e.g., back to the state shown in FIG. **12**A or a different state) via further manipulation/modulation (e.g., heating selected regions) of actuation element **1218**.

[0064] FIGS. **13**A and **13**B are partially schematic, cross-sectional views of a variable fluid resistor comprising a dual lumen elastomeric tube **1312** configured in accordance with still another embodiment of the present technology. More specifically, FIG. **13**A illustrates the elastomeric tube **1312** in an initial or low-resistance state before modulation. The elastomeric tube **1312** comprises a first lumen or a fluid flow-through lumen **1316** having an initial cross-sectional shape (e.g., a "D" shaped lumen). The elastomeric tube **1312** further comprises a second lumen or a control lumen **1336** adjacent the first lumen **1316** and a diaphragm therebetween. The control lumen **1336** contains one or more actuation elements **1318**. In the illustrated embodiment, for example, the actuation element **1318** is composed of SMM and includes a first or expansion portion **1314** and a second or shrinkage portion **1315**. Although only a single actuation element **1318** is shown in the cross-sectional views of FIGS. **13**A and **13**B, it will be appreciated that in further embodiments multiple actuation elements **618** can be arrayed serially along a length of the elastomeric tube **1312**.

[0065] FIG. **13**B illustrates the elastomeric tube **1312** in an increased or higher resistance state after activation of the actuation element **1318**. More specifically, non-invasive energy (e.g., heating via laser energy) has been used on expansion portion **1314** of the actuation element **1318**, thereby causing the actuation element **1318** to expand. Such expansion pushes the diaphragm toward the flow-through lumen **1316** and decreases the cross-sectional dimension of the flow-through lumen **1316**. This decrease in size of the flow-through lumen **1316** accordingly increases the fluid resistance through the lumen **1316**. The cross-sectional dimension of the flow-through lumen **1316** can be further modified via additional modulation of the actuation element **1318**. For example, fluid resistance through the flow-through lumen **1316** can be further decreased by additional heating of the expansion portion **1314** or returned to a lower resistance state via heating of the shrinkage portion **1315**.

[0066] In some FIG. **13**C illustrates another embodiment of an inflow mounted variable resistor **1320** in accordance with the present technology. In this embodiment, multiple actuation elements **618** can be arrayed serially along a length of control lumen **636** (FIG. **13**A). As the expansion portion **1314** of each target actuation element **1318** is actuated, the length of the restricted area is increased thereby increasing the fluid resistance linearly. Likewise, actuating shrinkage portion(s) **1315** of target actuation element(s) **1318** can decease fluid resistance. As shown in FIG. **13**C, such fluid controls can be incorporated into a shunt plate **1303**, inflow tube **1305**, an outflow mounted variable resistor **1321**, and/or the outflow tube (not shown).

[0067] FIG. **13**D illustrates a variable fluid resistor configured in accordance with still another embodiment of the present technology. The embodiment shown in FIG. **13**D can include a number of features similar to those of the variable fluid resistors described above with reference to FIGS. **13**A and **13**B. In this embodiment, however, the elastomeric tube **1312** comprises a single fluid flow-through lumen **1316**, while an actuation assembly **1322** positioned along the elastomeric tube **1312** comprises a dual-lumen arrangement similar to that described above. In particular, the actuation assembly **1322** comprises a first lumen **1316**′ having a predetermined cross-sectional shape (e.g., a "D" shaped lumen). The elastomeric tube **1312** is positioned within and extends through the first lumen **1316**′ of the actuation assembly **1322**. The actuation assembly **1322** further comprises a second lumen or a control lumen **1336**′ adjacent the first lumen **1316**′. The control lumen **1336**′ contains one or more actuation elements **1318** similar to the actuation elements described previously. In this embodiment, for example, the actuation element **1318** is composed of SMM and includes a first or expansion portion **1314** and a second or shrinkage portion **1315**.

[0068] Selectively heating the expansion portion **1314** can cause the actuation element **1318** to

expand. Like the arrangement described above with reference to FIGS. **13**A and **13**B, such expansion decreases the cross-sectional dimension of the elastomeric tube **1312** by driving the elastomeric tube **1312** away from the control lumen **1336**′ and toward fixed inner walls of the first lumen **1316**′. By decreasing the cross-sectional dimension of the elastomeric tube **1312**, fluid resistance through the tube **1312** is accordingly increased. The fluid resistance through elastomeric tube **1312** can be further decreased by additional heating of the expansion portion **1314**, or the elastomeric tube **1312** can be returned to a lower resistance state via heating of the shrinkage portion **1315** of actuation element **1318**. Although only a single actuation assembly **1322** is shown, it will be appreciated that in further embodiments multiple actuation assemblies **1322** can be positioned along a length of elastomeric tube **1312**.

[0069] FIGS. **13**E and **13**F are partially schematic, cross-sectional views of a fluid resistor comprising a dual lumen elastomeric tube **1312**′ configured in accordance with yet another embodiment of the present technology. The fluid resistor in the embodiment illustrated in FIGS. **13**E and **13**F operates using a similar principle to that described above with reference to FIGS. **13**A and **13**B. For example, FIG. **13**E illustrates the elastomeric tube **1312**′ in an initial or low-resistance state before modulation. The elastomeric tube **1312**′ comprises a first lumen or a fluid flow-through lumen **1316**′ having an initial cross-sectional shape (e.g., a "D" shaped lumen). The elastomeric tube **1312**′ further comprises a second lumen or a control lumen **1336**′ adjacent the first lumen **1316**. The control lumen **1336**′ is filled with a control fluid. Referring next to FIG. **13**F, when a volume of control fluid is increased, the cross-sectional dimension of the flow-through lumen **1316** is decreased as an elastomeric diaphragm **1337** expands into the flow-through lumen **1316**′, thereby increasing fluid resistance and decreasing flow through the lumen **1316**′. Likewise, when control fluid is removed from the control lumen **1336**′, the elastomeric diaphragm **1337** retracts and the cross-sectional dimension of the flow-through channel **1316**′ is increased, thereby reducing fluid resistance and increasing outflow through the lumen **1316**′. Control fluid can be removed or added to the control lumen **1336**′, for example, using a syringe. In some embodiments, one or more reservoirs (not shown) may be fluidly interfaced with the control lumen **1336**′ and fluid volume of the control lumen **1336**′ can be adjusted by adding or removing fluid from the reservoir(s). Further, it will be appreciated that in some embodiments fluid control systems configured in accordance with the present technology may comprise multiple fluid control sealed lumens serially distributed along the length of the control system.

[0070] FIGS. **14**A and **14**B illustrate yet another embodiment of a SMM-based actuator **1418** configured in accordance with the present technology and adapted for use in an adjustable flow glaucoma shunt. In this embodiment, the actuator **1418** comprises one or more coils **1424** arranged about a periphery of clamping arm **1423**. The coil(s) **1424** and clamping arm **1423** may both be composed of SMM. Anchors **1410** are positioned to fixedly hold the actuator **1418** in position on base **1411** such that the clamping arm **1423** is pressed against elastomeric flow-through tube **1412**. The elastomeric flow-through tube **1412** can have a stiffness that maintains the outer coils **1424** in a state comparable to the mounted state for the ribbon/wire actuators **1318** described above with reference to FIGS. **12**A-**13**B.

[0071] In operation, sections of the coil(s) **1424** can be selectively actuated to adjust the clamping pressure of the clamping arm **1423** against flow-through tube **1412**, and thereby the fluid resistance. Referring to FIG. **14**B, for example, coils **1424** on one side (e.g., the right side) of clamping arm **1423** can be heated via laser energy applied at target site **1413**. Such heating actuates the selected coils **1424** and causes them to coil more tightly, thereby actuating the clamping arm **1423** to increase pressure and increase resistance on the flow-through tube **1412**. Actuation of the coils **1424** on the other side of the clamping arm **1423** (the left side coils) relaxes the clamping arm **1423** and thereby decreases pressure and resistance on the flow-through tube **1412**.

[0072] In alternate embodiments, the actuator **1418** can be set in a rest or initial position such that the clamping arm **1423** completely occludes the flow-through **1412** and the coils **1424** can be

selectively adjusted to increase or decrease the tension of the clamping arm **1423** against the base **1411**. The base **1411** accordingly acts as an anvil as the clamping arm **1423** drives the flow-through tube **1412** against it during operation. In some embodiments, such an arrangement may be used to operate an adjustable opening pressure valve (not shown), which is set to selectively control the desired control Intraocular Pressure (IOP). In other embodiments, however, the actuator **1418** may have a different arrangement and/or include different features.

[0073] FIGS. **15**A-**15**C illustrate an adjustable glaucoma shunt **1500** configured in accordance with another embodiment of the present technology and include fluid resistor elements such as those described above with reference to FIGS. **14**A and **14**B. FIG. **15**A, for example, is an exploded view of the shunt **1500**, and FIG. **15**B is a top view of the assembled shunt **800**. Referring to FIGS. **15**A and **15**B together, the shunt **1500** comprises an elastomeric flow-through tube **1512** carried by and operably coupled with control assembly **1519**. The flow-through tube **1512** comprises an inflow region or inflow portion **1505** at one end of the flow-through tube **1512**, and an outflow assembly **1527** including one or more outflow ports **1502** at or near an opposite end of the flow-through tube **1512**.

[0074] The shunt **1500** also includes an actuator **1518** carried by and operably coupled to control assembly **1519**. The actuator **1518** can be similar to the actuator **1418** described above with reference to FIGS. **14**A and **14**B. In the illustrated embodiment, for example, actuator **1518** includes a clamping arm **1523** operably coupled to and positioned between a plurality of coils **1524**. The coils **1524** (like the coils **1424** described above) can be composed of SMM and adapted to selectively modulate the flow-through tube **1512** to increase/decrease pressure therethrough as described previously.

[0075] In the illustrated embodiment, the shunt **1500** includes a pressure port **1528** and corresponding pressure transducer **1529** configured to be positioned within a pressure transducer housing **1530** on the control assembly **1519**. The pressure port **1528**/pressure transducer **1529** are configured to provide pressure information to a clinician/operator during operation of the shunt **1500**. In other embodiments, the pressure port and/or pressure transducer **1529** may have a different arrangement relative to each other and the other components of the shunt **1500**. Further, the pressure port **1528**/pressure transducer **1529** are optional components that may not be included in some embodiments. In some embodiments, the shunt **1500** may also optionally include a differential port **1526** in the control assembly **1519**.

[0076] The shunt **1500** can further include a plate **1503** configured to be positioned over at least a portion of the control assembly **1518**, flow-through tube **1512**, and actuator **1518**. The plate **1503** can include a window **1531** such that when the shunt **1500** is assembled (as shown in FIG. **15**B), the window **1531** provides access to the actuator **1518** and other components carried by the control assembly **1519**.

[0077] FIG. **15**C illustrates an implant tool **1534** configured to deliver and position shunt **1500** within an eye capsule of a patient (not shown) in accordance with an embodiment of the present technology. The implant tool **1534** can include, for example, a guide needle **1532** configured to carry the shunt **1500** for delivery, and a guide needle release **1533** that an operator can actuate to release the shunt **1500** once at a desired position/orientation within the patient. In other embodiments, however, the implant tool **1534** may have a different configuration and/or the shunt **1500** may be delivered using other suitable devices/techniques.

[0078] FIGS. **16**A-**16**E illustrate various features of an adjustable glaucoma shunt **1600** configured in accordance with yet another embodiment of the present technology. The shunt **1600** can include a number of features similar to the shunt **1500** described above with reference to FIGS. **15**A-**15**C. For example, as best seen in FIG. **16**A, the shunt **1600** comprises a flow-through tube **1612** having an inflow port or inflow region **1601** at one end, and an outflow port **1602** at an opposite end of the flow-through tube **1612**. The shunt **1600** further comprises a control assembly **1619** configured to modulate flow through the flow-through tube **1612**. The flow-through tube **1612**, control assembly

1619, and a number of other components of the shunt are carried by plate **1603**.
[0079] The shunt **1600** differs from the shunt **1500**, however, in that the shunt **1600** includes a different system for modulating fluid flow along the flow-through tube **1612**. In particular, rather than the actuator **1518** including the clamping arm **1523**/coils **1524** described previously, the shunt **1600** in the present embodiment comprises an arrangement similar to that described above with reference to FIGS. **13**E and **13**F. Referring to FIGS. **16**B-**16**D, for example, the control assembly **1629** of shunt **1600** comprises a control fluid **1644** contained within a control fluid chamber **1636** comprising an annular region around a thin walled tubular flow-through channel of tube **1612**. The control fluid chamber **1636** is fluidly isolated from the flow-through channel. A reservoir **1643** is interfaced with and in fluid communication with the control fluid chamber. The reservoir **1643** is configured to provide a larger target for conveniently injecting or removing control fluid **1636** from the system. In operation, control fluid **1644** may be added/removed from the control fluid chamber **1636** to increase/decrease a fluid cross-sectional dimension of an aqueous flow path **1616** through flow-through channel **1612**, thereby decreasing/increasing the corresponding fluid flow therethrough.
[0080] In some embodiments, a solid core may optionally be introduced into flow path **1616** to initially reduce the fluid cross-sectional dimension even further and thereby make the flow path more sensitive to small changes in the diameter of flow-through channel **1612**. In FIG. **16**E, for example, optional solid core pin or element **1637** has been introduced into the flow-through channel **1612** and flow path **1616** now has an annular cross-sectional profile.
[0081] In the illustrated embodiment, the shunt **1600** further comprises a pressure transducer **1629**. The pressure transducer **1629** is an optional component that may not be included in some embodiments. Further, it will be appreciated that shunt **1600** may include features other than those described herein and/or the features of shunt **1600** may have a different arrangement relative to each other.
[0082] In many of the embodiments described herein, the actuators or fluid resistors are configured to compress or “pinch” the drainage tube during operation. In this way, the actuators/fluid resistors can incrementally or continuously change the flow resistance through the drainage tube to selectively regulate pressure/flow. The actuators and fluid resistors configured in accordance with the present technology can accordingly adjust the level of resistance or compression between a number of different positions, and accommodate a multitude of variables (e.g., IOP, aqueous production rate, native aqueous outflow resistance, and/or native aqueous outflow rate) to precisely regulate flow rate through the drainage tube.
[0083] The disclosed actuators and fluid resistors can all be operated using non-invasive energy. This feature allows such devices to be implanted in the patient and then modified/adjusted over time without further invasive surgeries or procedures for the patient. Further, because the devices disclosed herein may be actuated via non-invasive energy, such devices do not require any additional power to maintain a desired orientation or position. Rather, the actuators/fluid resistors disclosed herein can maintain a desired position/orientation without power. This can significantly increase the usable lifetime of such devices and enable such devices to be effective long after the initial implantation procedure.
EXAMPLES
[0084] Several aspects of the present technology are set forth in the following examples.
[0085] 1. An adjustable flow shunt for treating glaucoma in a human patient, the shunt comprising:
[0086] an elongated outflow drainage tube having a proximal inflow region and a distal outflow region; and [0087] an inflow control assembly at the proximal inflow region, wherein the inflow control assembly comprises— [0088] a control element sized and shaped to slidably engage the proximal inflow region; and [0089] a spring element operably coupled between the control element and an anchor element engaged with the proximal inflow region; [0090] wherein the proximal inflow region comprises one or more apertures defining a fluid inlet area positioned to allow fluid

to flow therethrough and into the outflow drainage tube, [0091] wherein the spring element is configured to be activated by a non-invasive energy and, upon activation, slidably actuate the control element along the proximal inflow region such that (a) the one or more apertures are accessible and have a first fluid flow cross-section or (b) the one or more apertures are at least partially covered by the control element and have a second fluid-flow cross-section less than the first fluid flow cross-section.

[0092] 2. The adjustable flow shunt of example 1 wherein the proximal inflow region comprises a core element operably coupled to and extending from a proximal end of the outflow drainage tube, and wherein the one or more apertures extend through a sidewall of the core element to define the fluid inlet area.

[0093] 3. The adjustable flow shunt of example 2 wherein the core element is composed of a different material than the outflow drainage tube.

[0094] 4. The adjustable flow shunt of example 2 wherein the core element is composed of a first material having a first rigidity, and wherein the outflow drainage tube is composed of a second material having a second rigidity less than the first rigidity.

[0095] 5. The adjustable flow shunt of example 2 wherein the core element is composed of polyether ether ketone (PEEK), acrylic, polycarbonate, metal, ceramic, quartz, and/or sapphire.

[0096] 6. The adjustable flow shunt of any one of examples 1-5 wherein the elongated outflow drainage tube is composed of silicone and/or urethane.

[0097] 7. The adjustable flow shunt of any one of examples 1-6 wherein the spring element is composed of a shape memory material.

[0098] 8. The adjustable flow shunt of any one of examples 1-6 wherein the spring element is composed of nitinol.

[0099] 9. The adjustable flow shunt of any one of examples 1-8 wherein the inflow control assembly is configured for placement within an anterior chamber in a region outside of the optical field of view of the eye.

[0100] 10. The adjustable flow shunt of example 9 wherein the outflow drainage tube is sized and shaped to traverse a region between the anterior chamber to a region in a suprachoroidal location of the eye.

[0101] 11. The adjustable flow shunt of example 9 wherein the outflow drainage tube is sized and shaped to traverse a region between the anterior chamber to a region in a subconjunctival location of the eye.

[0102] 12. The adjustable flow shunt of any one of examples 1-11 wherein the one or more apertures comprises a single elongated slot extending axially along the proximal inflow region.

[0103] 13. The adjustable flow shunt of any one of examples 1-11 wherein the one or more apertures comprises a plurality of apertures extending radially about the proximal inflow region.

[0104] 14. The adjustable flow shunt of any one of examples 1-11 wherein the one or more apertures comprises a plurality of apertures extending helically about the proximal inflow region.

[0105] 15. The adjustable flow shunt of any one of examples 1-14 wherein the spring element is configured to be activated via laser energy.

[0106] 16. The adjustable flow shunt of any one of examples 1-15 wherein the spring element comprises a first spring and the anchor comprises a first anchor, and wherein the first spring and first anchor are positioned on a first side of the control element, and wherein the inflow control assembly further comprises: [0107] a second spring and a corresponding second anchor on a second, opposite side of the control element; [0108] wherein the first and second spring elements are configured to be selectivity activated by non-invasive energy and, upon activation, slidably move the control element along the proximal inflow region in a first direction or a second direction, respectively, such that (a) the one or more apertures have the first fluid flow cross-section, or (b) the one or more apertures are at least partially covered by the control element and have the second fluid-flow cross-section less than the first fluid flow cross-section.

[0109] 17. The adjustable flow shunt of example 16 wherein the first and second spring elements are configured such that, upon activation, the control element slidably moves the control element along the proximal inflow region such that the one or more apertures are fully covered and inaccessible.
[0110] 18. The adjustable flow shunt of any one of examples 1-15 wherein the spring element and corresponding anchor element are positioned on a proximal end of the control element between the control element and the outflow drainage tube.
[0111] 19. The adjustable flow shunt of any one of examples 1-15 wherein the spring element comprises one or more coil springs extending about the proximal inflow region.
[0112] 20. The adjustable flow shunt of any one of examples 1-15 wherein the spring element comprises one or more elongated bow springs extending between the control element and the anchor element.
[0113] 21. An adjustable flow shunt assembly for treatment of glaucoma, the shunt assembly comprising: [0114] an elongated drainage tube having a proximal portion and a distal portion, wherein the proximal portion includes an inflow port configured to be in fluid communication with a fluid chamber in an eye of the patient; [0115] a variable resistor assembly configured to selectively control flow of fluid into the inflow port, wherein the variable resistor assembly comprises— [0116] a base portion; [0117] an aperture plate carried by the base portion, wherein the aperture plate comprises a plurality of first apertures extending therethrough; [0118] a standoff plate carried by and extending away from the aperture plate, wherein the standoff plate comprises a plurality of second apertures extending therethrough, and wherein the second apertures are aligned with corresponding first apertures of the aperture plate; and [0119] a membrane disposed on a carried by the standoff plate, wherein the membrane is positioned to sealably cover an open end of each of the second apertures; [0120] wherein, during operation, a portion of the membrane over one or more second apertures of the standoff plate is configured to be selectively targeted and removed via non-invasive energy, thereby creating a fluid path from the site of fluid in the patient through the accessible open ends of the targeted second apertures, the corresponding first apertures, and into the drainage tube.
[0121] 22. The adjustable flow shunt assembly of example 21 wherein: [0122] the first apertures have a first cross-sectional dimension; and [0123] the second apertures have a second cross-sectional dimension greater than the first cross-sectional dimension.
[0124] 23. The adjustable flow shunt assembly of example 21 wherein the first apertures have identical cross-sectional dimensions.
[0125] 24. The adjustable flow shunt assembly of any one of examples 21-23 wherein the standoff plate is composed, at least in part, of a hydrophobic material configured to be at least partially melted via non-invasive energy.
[0126] 25. The adjustable flow shunt assembly of any one of examples 21-23 wherein the standoff plate is composed, at least in part, of a wax material configured to be at least partially melted via non-invasive energy.
[0127] 26. The adjustable flow shunt assembly of any one of examples 21-23 wherein the base portion, aperture plate, and standoff plate of the variable resistor assembly are separate, discrete components operably coupled together.
[0128] 27. The adjustable flow shunt assembly of any one of examples 21-23 wherein the standoff plate and membrane are fabricated as a single, unitary component composed of the same material.
[0129] 28. The adjustable flow shunt assembly of any one of examples 21-23 wherein the aperture plate and standoff plate are fabricated as a single, unitary component composed of the same material.
[0130] 29 The adjustable flow shunt assembly of any one of examples 21-28 wherein: [0131] the membrane further comprises a plurality of target indicia aligned with and corresponding with individual second apertures; and [0132] during operation, the non-invasive energy is delivered to

corresponding target indicia of the membrane to selectively remove membrane material at the targeted location.

[0133] 30. An adjustable flow shunt for treatment of glaucoma in a human patient, the adjustable flow shunt comprising: [0134] an elongated outflow tube having (a) a proximal inflow portion configured for placement within an anterior chamber in a region outside of an optical field of view of an eye of the patient, and (b) a distal outflow portion at a different location of the eye; and [0135] an actuator positioned along the outflow tube between the inflow portion and the outflow portion, wherein the actuator is transformable between an open position that allows fluid to flow through the outflow tube and resistance positions that partially obstruct fluid flow through the outflow tube, [0136] wherein during operation, the actuator is movable between positions in response to non-invasive energy.

[0137] 31 The adjustable flow shunt of example 30 wherein the actuator is configured to partially obstruct fluid flow through the outflow tube in the resistance positions by engaging the outflow tube and changing a diameter and/or a cross-sectional shape of the outflow tube.

[0138] 32. The adjustable flow shunt of example 30 or example 31 wherein the actuator is movable between positions in response to laser energy.

[0139] 33. The adjustable flow shunt of example 30 wherein: [0140] the outflow tube comprises a dual lumen tube having a first lumen for carrying fluid therethrough and a second lumen adjacent to the first lumen and separated by the first lumen by a diaphragm; [0141] the actuator is positioned within the second lumen, and wherein the actuator comprises one or more actuation elements configured to transform between and expanded state and an initial state in response to the non-invasive energy, [0142] in the expanded state, actuation elements engage and push the diaphragm toward the first lumen and decrease a cross-sectional dimension thereof.

[0143] 34. The adjustable flow shunt of any one of examples 30-33 wherein the actuator is configured to hold the open position or one of the resistance positions without power.

[0144] 35. An adjustable flow shunt, comprising: [0145] an elongated outflow tube having a proximal inflow portion configured for placement at a first location within an eye of the patient, and a distal outflow portion at a second location of the eye spaced apart from the first location, [0146] wherein the outflow tube comprises a dual lumen tube having a first lumen for carrying fluid therethrough and a second lumen adjacent to the first lumen and fluidly isolated from the first lumen; and [0147] a control fluid disposed within the second lumen, [0148] and wherein, during operation— [0149] increasing a volume of control fluid within the second lumen decreases a cross-sectional dimension of the first lumen, thereby partially obstructing fluid flow through the first lumen, and [0150] decreasing a volume of control fluid within the second lumen increases a cross-sectional dimension of the first lumen, thereby increasing fluid flow through the first lumen.

[0151] 36. The adjustable flow shunt of example 35 wherein the elongated outflow tube comprises an elastomeric tube.

[0152] 37 The adjustable flow shunt of example 35 or example 36, further comprising a reservoir in fluid communication with the second lumen, and wherein the volume of control fluid within the second lumen is changed by transferring control fluid to and/or from the reservoir.

[0153] 38. The adjustable flow shunt of any one of examples 35-37 wherein the volume of control fluid within the second lumen is changed by transferring control fluid to and/or from the second lumen via a syringe.

[0154] 39 The adjustable flow shunt of any one of examples 35-38 wherein the first lumen is separated from the second lumen by a diaphragm, and wherein: [0155] increasing a volume of control fluid within the second lumen moves the diaphragm toward the first lumen and decreases a cross-sectional dimension thereof; and [0156] decreasing a volume of control fluid within the second lumen moves the diaphragm away from the first lumen and increases a cross-sectional dimension thereof.

[0157] 40. A shunt for treatment of glaucoma in a human patient, the shunt comprising: [0158] an

elongated outflow drainage tube having a proximal inflow region and a distal outflow region; [0159] an inflow control assembly at the proximal inflow region; and [0160] a transition region along the outflow tube between the inflow region and the outflow region, wherein, during operation, the transition region is transformable between a first generally linear delivery shape and a second shape different than the first shape to anchor the shunt at a desired location of the eye.
[0161] 41 The shunt of example 40 wherein the outflow drainage tube is configured to be delivered via guidewire, and wherein the transition region is configured to transform between the first delivery shape and the second shape upon removal of the guidewire.
[0162] 42 The shunt of example 40 or example 41 wherein the transition region is configured to transform between the first delivery shape and the second shape upon application of non-invasive energy to one or more selected areas of the transition region.
[0163] 43 The shunt of example 40 or example 41 wherein the transition region is configured to transform between the first delivery shape and the second shape in response to application of non-invasive laser energy to one or more selected areas of the transition region.
[0164] 44. The shunt of any one of examples 40-43 wherein the second shape comprises a generally “L” shaped configuration.
CONCLUSION
[0165] The above detailed description of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, any of the features of the variable flow shunts described herein may be combined with any of the features of the other variable flow shunts described herein and vice versa. Moreover, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.
[0166] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions associated with variable flow shunts have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.
[0167] Moreover, unless the word “or” is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of “or” in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term “comprising” is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

Claims

1-22. (canceled)
23. An actuator assembly for selectively modifying fluid flow through a shunt configured to be implanted in a human patient, the actuator assembly comprising: a control element; a first shape memory actuation element operably coupled to the control element and configured to be selectively

and non-invasively activated to move the control element in a first direction; and a second shape memory actuation element operably coupled to the control element and configured to be selectively and non-invasively activated to move the control element in a second direction, different than the first direction.

24. The actuator assembly of claim 23 wherein the control element, the first shape memory actuation element, and the second shape memory actuation element form a unitary structure.

25. The actuator assembly of claim 24 wherein the unitary structure is composed of Nitinol.

26. The actuator assembly of claim 23 wherein: the first shape memory actuation element is configured to transition between a martensitic state and a shape memory state in response to being selectively and non-invasively activated, and the second shape memory actuation element is configured to transition between a martensitic state and a shape memory state in response to being selectively and non-invasively activated.

27. The actuator assembly of claim 23 wherein: the control element is configured to slidably move in the first direction in response to the first shape memory actuation element being selectively and non-invasively activated, and the control element is configured to slidably move in the second direction in response to the second shape memory actuation element being selectively and non-invasively activated.

28. The actuator assembly of claim 23 wherein, when implanted in the patient, selectively and non-invasively activating the first shape memory actuation element and/or the second shape memory actuation element selectively modifies fluid resistance through the shunt.

29. The actuator assembly of claim 23 wherein the actuator assembly is sized and shaped for use within an intraocular shunt configured to be implanted within a patient's eye.

30. An actuator assembly for selectively modifying fluid flow through a shunt configured to be implanted in a human patient, the actuator assembly comprising: a control element; a first shape memory actuation element operably coupled to the control element and configured to be selectively and non-invasively activated to undergo a first shape change toward a first set shape to move the control element in a first direction; and a second shape memory actuation element operably coupled to the control element and configured to be selectively and non-invasively activated to undergo a second shape change toward a second set shape to move the control element in a second direction, different than the first direction.

31. The actuator assembly of claim 30 wherein the control element, the first shape memory actuation element, and the second shape memory actuation element form a unitary structure.

32. The actuator assembly of claim 31 wherein the unitary structure is composed of Nitinol.

33. The actuator assembly of claim 30 wherein at least one of the first shape memory actuation element or the second shape memory actuation element is configured to transition between a martensitic state and a shape memory state in response to being selectively and non-invasively activated

34. The actuator assembly of claim 30 wherein: the first shape memory actuation element is configured to slidably move the control element in the first direction when selectively and non-invasively activated, and the second shape memory actuation element is configured to slidably move the control element in the second direction when selectively and non-invasively activated.

35. The actuator assembly of claim 30 wherein, when implanted in the patient, selectively and non-invasively activating the first shape memory actuation element and/or the second shape memory actuation element selectively modifies fluid resistance through the shunt.

36. The actuator assembly of claim 30 wherein the actuator assembly is sized and shaped for use within an intraocular shunt configured to be implanted within a patient's eye.

37. An actuator assembly for selectively modifying fluid flow through a shunt configured to be implanted in a human patient, the actuator assembly comprising: a control element; a first shape memory actuation element operably coupled to the control element and configured to be selectively and non-invasively activated to undergo a first shape change toward a first set shape to move the

control element in a first direction; and a second shape memory actuation element operably coupled to the control element and configured to be selectively and non-invasively activated to undergo a second shape change toward a second set shape to move the control element in a second direction, different than the first direction, wherein the actuator assembly is configured such that: the first shape memory actuation element transitions away or further away from the first set shape in response to the second shape memory actuation element being selectively and non-invasively activated, and the second shape memory actuation element moves away or further away from the second set shape in response to the first shape memory actuation element being selectively and non-invasively activated.

38. The actuator assembly of claim 37 wherein the control element, the first shape memory actuation element, and the second shape memory actuation element form a unitary structure.

39. The actuator assembly of claim 37 wherein the actuator assembly is further configured such that a combined length of the first shape memory actuation element and the second shape memory actuation element remains the same or about the same (a) in response to the first shape memory actuation element being selectively and non-invasively activated and (b) in response to the second shape memory actuation element being selectively and non-invasively activated.

40. The actuator assembly of claim 37 wherein: the first shape memory actuation element is configured to slidably move the control element in the first direction when selectively and non-invasively activated, and the second shape memory actuation element is configured to slidably move the control element in the second direction when selectively and non-invasively activated.

41. The actuator assembly of claim 37 wherein, when implanted in the patient, selectively and non-invasively activating the first shape memory actuation element and/or the second shape memory actuation element selectively modifies fluid resistance through the shunt.

42. The actuator assembly of claim 37 wherein the actuator assembly is sized and shaped for use within an intraocular shunt configured to be implanted within a patient's eye.