COIL IMPLANT FOR GLAUCOMA TREATMENT

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ABSTRACT

Systems and methods for delivering a coiled implant into an eye are disclosed. A method of forming an implant within the eye can include introducing a distal end portion of an elongate tube into said eye; passing a substantially straight, uncoiled wire through the tube; and forming a coiled implant as the wire emerges from the distal end portion of the tube, while the distal end portion is disposed in the eye.
COIL IMPLANT FOR GLAUCOMA TREATMENT

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims the priority benefit of U.S. Provisional Application No. 60/475,513, filed Jun. 2, 2003, and entitled “Injectable Wire Stent for Treating Glaucoma and Methods of Use,” the entirety of which is hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The invention relates generally to improved medical devices and methods for the treatment of glaucoma.

BACKGROUND OF THE INVENTION

[0003] The human eye is a specialized sensory organ capable of light reception and able to receive visual images. The trabecular meshwork serves as a drainage channel and is located in anterior chamber angle formed between the iris and the cornea. The trabecular meshwork maintains a balanced pressure in the anterior chamber of the eye by draining aqueous humor from the anterior chamber.

[0004] About two percent of people in the United States have glaucoma. Glaucoma is a group of eye diseases that causes pathological changes in the optic disk and corresponding visual field loss resulting in blindness if untreated. Intraocular pressure elevation is the major etiologic factor in all glaucomas.

[0005] In glaucomas associated with an elevation in eye pressure the source of resistance to outflow is in the trabecular meshwork. The tissue of the trabecular meshwork allows the “aqueous” to enter Schlemm’s canal, which then empties into aqueous collector channels in the posterior wall of Schlemm’s canal and then into aqueous veins. The aqueous or aqueous humor is a transparent liquid that fills the region between the cornea at the front of the eye and the lens. The aqueous humor is constantly secreted by the ciliary body around the lens, so there is a continuous flow of the aqueous humor from the ciliary body to the eye’s front chamber. The eye’s pressure is determined by a balance between the production of aqueous and its exit through the trabecular meshwork (major route) or via uveal scleral outflow (minor route). The trabecular meshwork is located between the outer rim of the iris and the internal periphery of the cornea. The portion of the trabecular meshwork adjacent to Schlemm’s canal causes most of the resistance to aqueous outflow (juxtacanalicular meshwork).

[0006] Glaucoma is grossly classified into two categories: closed-angle glaucoma and open-angle glaucoma. The closed-angle glaucoma is caused by closure of the anterior angle by contact between the iris and the inner surface of the trabecular meshwork. Closure of this anatomical angle prevents normal drainage of aqueous humor from the anterior chamber of the eye. Open-angle glaucoma is any glaucoma in which the angle of the anterior chamber remains open, but the exit of aqueous through the trabecular meshwork is diminished. The exact cause for diminished filtration is unknown for most cases of open-angle glaucoma. However, there are secondary open-angle glaucomas that may include edema or swelling of the trabecular spaces (from steroid use), abnormal pigment dispersion, or diseases such as hyperthyroidism that produce vascular congestion.

[0007] All current therapies for glaucoma are directed at decreasing intraocular pressure. This is initially by medical therapy with drops or pills that reduce the production of aqueous humor or increase the outflow of aqueous. However, these various drug therapies for glaucoma are sometimes associated with significant side effects, such as headache, blurred vision, allergic reactions, death from cardiopulmonary complications and potential interactions with other drugs. When the drug therapy fails, surgical therapy is used. Surgical therapy for open-angle glaucoma consists of laser ( trabeculoplasty), trabeculectomy and aqueous shunting implants after failure of trabeculectomy or if trabeculectomy is unlikely to succeed. Trabeculectomy is a major surgery that is most widely used and is augmented with topically applied anticeancer drugs such as 5-fluorouracil or mitomycin-c to decrease scarring and increase surgical success.

[0008] Approximately 100,000 trabeculectomies are performed on Medicare age patients per year in the United States. This number would increase if the morbidity associated with trabeculectomy could be decreased. The current morbidity associated with trabeculectomy consists of failure (10-15%), infection (a life long risk about 2-5%), choroidal hemorrhage (1%, a severe internal hemorrhage from pressure too low resulting in visual loss), cataract formation, and hypotony maculopathy (potentially reversible visual loss from pressure too low).

[0009] If it were possible to bypass the local resistance to outflow of aqueous at the point of the resistance and use existing outflow mechanisms, surgical morbidity would greatly decrease. The reason for this is that the episcleral aqueous veins have a backpressure that would prevent the eye pressure from going too low. This would virtually eliminate the risk of hypotony maculopathy and choroidal hemorrhage. Furthermore, visual recovery would be very rapid and risk of infection would be very small (a reduction from 2-5% to 0.05%). Because of these reasons surgeons have tried for decades to develop a workable surgery for the trabecular meshwork.

[0010] The previous techniques, which have been tried, are goniotomy/trabeculotomy, and other mechanical disruption of the trabecular meshwork, such as trabeculopuncture, gonioscleral ablation, laser trabecular ablation and goniocurette. They are briefly described below.

[0011] Goniotomy/Trabeculotomy: Goniotomy and trabeculotomy are simple and directed techniques of microsurgical dissection with mechanical disruption of the trabecular meshwork. These initially had early favorable responses in the treatment of open-angle glaucoma. However, long-term review of surgical results showed only limited success in adults. In retrospect, these procedures probably failed secondary to repair mechanisms and a process of “filling in”. The filling in is the result of a healing process, which has the detrimental effect of collapsing and closing in of the created opening throughout the trabecular meshwork. Once the created openings close, the pressure builds back up and the surgery fails.

[0012] Trabeculopuncture: Q-switched Neodymium (Nd):YAG lasers also have been investigated as an optically invasive technique for creating full-thickness holes in trabecular meshwork. However, the relatively small hole created by this trabeculopuncture technique exhibits a filling in effect and fails.
[0013] Gonioophotoblation/Laser Trabecular Ablation: Gonioophotoblation is disclosed by Berlin in U.S. Pat. No. 4,846,172, and describes the use of an excimer laser to treat glaucoma by ablating the trabecular meshwork. This was not demonstrated by clinical trial to succeed. Hill et al. used an Erbium:YAG laser to create full thickness holes through trabecular meshwork (Hill et al., Lasers in Surgery and Medicine 11:341-346, 1991). This technique was investigated in a primate model and a limited human clinical trial at the University of California, Irvine. Although morbidity was zero in both trials, success rates did not warrant further human trials. Failure again was from filling in of created defects in trabecular meshwork by repair mechanisms. Neither of these is a valid surgical technique for the treatment of glaucoma.

[0014] Gonioscopy: This is an ab-interno (from the inside) mechanical disruptive technique. This uses an instrument similar to a cyclodialysis spatula with a microcurette at the tip. Initial results are similar to trabeculectomy that fails secondary to repair mechanisms and a process of filling in.

[0015] Although trabeculectomy is the most commonly performed filtering surgery, Viscosocanulostomy (VC) and non-penetrating trabeculotomy (NPT) are two new variations of filtering surgery. These are ab-externo (from the outside), major ocular procedures in which Schlemm’s canal is surgically exposed by making a large and very deep scleral flap. In the VC procedure, Schlemm’s canal is cannulated and viscoelastic drug injected (which dilates Schlemm’s canal and the aqueous collector channels). In the NPT procedure, the inner wall of Schlemm’s canal is stripped off after surgically exposing the canal.

[0016] Trabeculectomy, VC, and NPT are performed under a conjunctival and scleral flap, such that the aqueous humor is drained onto the surface of the eye or into the tissues located within the lateral wall of the eye. Normal physiological outflows are not used. These surgical operations are major procedures with significant ocular morbidity. When Trabeculectomy, VC, and NPT are thought to have a low chance for success, a number of implantable drainage devices have been used to ensure that the desired filtration and outflow of aqueous humor through the surgical opening will continue. The risk of placing a glaucoma drainage implant also includes hemorrhage, infection and postoperative double vision that is a complication unique to drainage implants.

[0017] All of the above embodiments and variations thereof have numerous disadvantages and moderate success rates. They involve substantial trauma to the eye and require great surgical skill by creating a hole over the full thickness of the sclera/cornea into the subconjunctival space. Furthermore, normal physiological outflow pathways are not used. The procedures are mostly performed in an operating room generating a facility fee, anesthesiologist’s professional fee and have a prolonged recovery time for vision. The complications of filtration surgery have inspired ophthalmic surgeons to look at other approaches to lowering intraocular pressure.

[0018] The trabecular meshwork and juxtacanalicular tissue together provide the majority of resistance to the outflow of aqueous and, as such, are logical targets for surgical removal in the treatment of open-angle glaucoma. In addition, minimal amounts of tissue are altered and existing physiologic outflow pathways are utilized. Trabecular bypass surgery has the potential for much lower risks of choroidal hemorrhage, infection and uses existing physiologic outflow mechanisms. This surgery could be performed under topical anesthesia in a physician’s office with rapid visual recovery.

[0019] The microsurgery disclosed in the prior art has a common disadvantage of using a medium-sized applicator for creating an opening in the trabecular meshwork. The implantation of a glaucoma stent would be better served if no applicator or a micro-sized applicator were used for creating an opening in the trabecular meshwork. Therefore, there is a great clinical need for the treatment of glaucoma by an injectable trabecular stent implantation in either an ab interno or ab externo procedure.

SUMMARY OF THE INVENTION

[0020] Some embodiments of the invention relate to a method of delivering a coil wire stent through trabecular meshwork of an eye, comprising the steps of: providing a coil wire stent, the coil wire stent being releasably coiled from an essentially straightened, uncoiled shape to a coiled shape configured to have an elongate lumen-like inner space, the coil wire stent being configured to permit aqueous flow in a direction from an anterior chamber to Schlemm’s canal through the elongate inner space; inserting the coil wire stent at the uncoiled, essentially straightened shape inside an applicator; passing the applicator through at least a portion of the trabecular meshwork; and deploying the coil wire stent to a desired location with the coil wire stent in the coiled shape.

[0021] In some embodiments, the step of passing the applicator is carried out by approaching the applicator from the anterior chamber toward the trabecular meshwork.

[0022] In some embodiments, the step of passing the applicator is carried out by approaching the applicator from Schlemm’s canal toward the trabecular meshwork.

[0023] In some embodiments, the step of deploying the coil wire stent in the uncoiled, essentially straightened shape to a desired location is via injection.

[0024] In some embodiments, the step of passing the applicator is guided with a guidewire into trabecular meshwork and/or Schlemm’s canal.

[0025] Some embodiments of the invention relate to a method and an applicator for deploying multiple coil wire stents within the eye. In an embodiment, the method for deploying multiple coil wire stents is for multiple stent placement within the eye. In some embodiments, the stents are placed about equally spaced along the circumference of the eye. In another embodiment, the stents are placed near regions of collector channels that are connected to Schlemm’s canal.

[0026] In some embodiments, the step of deploying the coil wire stent is carried out by retracting the applicator so that the deployed stent is stationary axially relative to the surrounding tissue.
In some embodiments, the coil wire stent is self-coiling. In some embodiments, the coil wire stent is made of a shape memory material that is coilably preshaped so as to become coiled after being delivered out of the applicator when the stent is heated to above the shape transitional temperature.

In some embodiments, the coil wire stent is made of shape memory material that is deployed out of the applicator in an essentially straightened, uncoiled shape into Schlemm’s canal, followed by a step of first heating the middle portion to above the shape transitional temperature to initiate the recoiling process at the middle section.

In some embodiments, the coil wire stent is made of shape memory material that is coilably preshaped so as to become coiled after being delivered out of the applicator when the constraint from the applicator is released.

In some embodiments, the coil wire stent is made of a biodegradable elastic material that is coilably preshaped so as to become coiled after being delivered out of the applicator when the constraint from the applicator is released. The opening occupied by the stent becomes a permanent configuration and maintains its openness after the stent biodegrades.

In some embodiments, the coil wire stent comprises a tip at its distal end, wherein the tip is sized and configured to exert a force atraumatic to the surrounding tissue.

In some embodiments, the cross-sectional configuration of the coil strut is not round, preferably in an oval or kidney shape.

In some embodiments, the coil wire stent comprises a plurality of sections, each section comprising varying properties in loop cross-sectional configuration, strut cross-sectional configuration, loop diameter, strut diameter, strength, material composition, conductivity, shape transitional temperature, and like.

In some embodiments, the coil wire stent comprises a broad scope of non-straight wire stents, such as a zigzag shape, a random shape, an irregular shape, a shape with crossing-over wires or the like.

In some embodiments, a distal end of the coil wire stent is in Schlemm’s canal.

In some embodiments, the method further comprises a step of piercing an opening at cornea for the applicator to pass through before the step of passing the applicator through at least a portion of the trabecular meshwork. In one embodiment, the opening at cornea is less than 1 mm. In another embodiment, the opening at cornea is less than 0.75 mm. In still another embodiment, the opening at cornea is less than 0.5 mm.

Some embodiments of the invention relate to a method of delivering a plurality of coil wire stents through trabecular meshwork of an eye, comprising the steps of: providing the plurality of coil wire stents, each coil wire stent being releasably coileable from an uncoiled shape to a coiled shape configured to have an elongate inner space, the coil wire stent being configured to permit aqueous flow in a direction from an anterior chamber to Schlemm’s canal; inserting the coil wire stents at the uncoiled shape inside an applicator in series; passing the applicator through at least a portion of the trabecular meshwork; and deploying a plurality of the coil wire stents to a desired coil wire stent location with the first coil wire stent in the coiled shape.

In some embodiments, the method further comprises deploying a second coil wire stent by the steps of: slightly removing the applicator out of the trabecular meshwork; directing a distal end of the applicator toward a second location on the trabecular meshwork; passing the applicator through at least a portion of the trabecular meshwork at the second location; and deploying the second coil wire stent with the coil wire stent in the coiled shape.

Some embodiments of the invention relate to a coil wire stent to divert aqueous humor in an eye from the anterior chamber into Schlemm’s canal, the coil wire stent comprising a distal section having at least one terminal aspect sized and shaped to be received within a portion of Schlemm’s canal and a proximal section having at least one terminal aspect sized and shaped to be received within the anterior chamber of the eye, wherein the coil wire stent permits fluid communication from the proximal section in the anterior chamber to the distal section in Schlemm’s canal. In one embodiment, at least a portion of the distal zone of the coil wire stent extends along Schlemm’s canal for some distance. The coil portion lying along and within Schlemm’s canal could act to support and dilate the canal and could be less tightly coiled so as to provide aqueous flow through the coil and into collector ducts.

Some embodiments of the invention relate to a coil wire stent made of a plurality of nanosprings that are deployable from a stent applicator. In some embodiments the nanosprings are up to several millimeters long, about 10-60 nm wide, and about 5-20 nm thick. In one embodiment, at least one end of the nanosprings is secured together to form the coil wire stent of the invention.

Some embodiments of the invention relate to a trabecular stent system to divert aqueous humor in an eye from the anterior chamber into Schlemm’s canal, comprising: a coil wire stent comprising a distal section having at least one terminal aspect sized and shaped to be received within a portion of Schlemm’s canal and a proximal section having at least one terminal aspect sized and shaped to be received within the anterior chamber of the eye; a delivery applicator having a distal end and a lumen, the delivery applicator being configured to hold the coil wire stent at an essentially uncoiled shape; and wherein the coil wire stent permits fluid communication from the proximal section in the anterior chamber to the distal section in Schlemm’s canal. In some embodiments, the applicator is configured to hold a plurality of coil wire stents.

Some embodiments of the invention relate to a coil wire stent that is flattenable when loaded into the applicator (also known as inserter), such that the coil configuration still exists but the coil struts are all lying along the axis (its appearance would be that of a spring that has been stepped...
on) with the inserter needle having an oval or non-round cross-section so as to reduce the incision size required. In one embodiment, regarding the insertion of the stent into the trabecular meshwork, the applicator tip could be stopped prior to penetrating the meshwork, allowing the wire of the stent to penetrate the meshwork and form a lumen as it coils.

[0045] Some embodiments of the invention relate to use of the coil wire stent that is not deformed when placed within the applicator, wherein the stent is rotatable when being deployed out of the applicator. In one embodiment, the step of deployment is carried out by using a rotating plunger to essentially screw the stent through the meshwork and using the rotary motion to help self-guide the stent along Schlemm’s canal.

[0046] Some embodiments of the invention relate to a method of delivering a coil wire stent through trabecular meshwork of an eye, comprising the steps of: providing a coil wire stent, the coil wire stent being releasably coilable from an essentially straightened, uncoiled shape to a coiled shape configured to have an elongate luminal-like inner space; the coil wire stent being configured to permit aqueous flow in a direction from an anterior chamber to Schlemm’s canal through the elongate inner space; inserting the coil wire stent at the uncoiled, essentially straightened shape inside an applicator; passing the applicator through scleral tissue into Schlemm’s canal; and deploying the coil wire stent through trabecular meshwork by diverting the tip facing and piercing through the outer wall of the trabecular meshwork with the coil wire stent in the coiled shape.

[0047] Some embodiments of the invention relate to a method of stenting a body channel, conduit, opening, or cavity by delivering a coil wire stent to the cavity, comprising the steps of: providing a coil wire stent, the coil wire stent being releasably coilable from an essentially straightened, uncoiled shape to a coiled shape configured to have an elongate luminal-like inner space; inserting the coil wire stent at the uncoiled, essentially straightened shape inside an applicator, cannula, injector, or catheter; passing the applicator through at least a portion of the body cavity; and deploying the coil wire stent to a desired location with the coil wire stent in the coiled shape.

[0048] In some embodiments, the body channel is selected from a group consisting of vascular vessels, arteries, veins, capillaries, trachea, esophagus, uterus, ureter, Fallopian tubes, urethra, intestines, colon, and the like.

[0049] Some embodiments of the invention include a method of treating glaucoma, comprising introducing an implant material through an opening in an eye; modifying a configuration of the implant material within the eye to form an implant having different configuration; positioning the implant to enhance drainage from anterior chamber to Schlemm’s canal.

[0050] In some embodiments the implant has a diameter substantially greater than the diameter of the opening. In some embodiments the modifying comprises converting a substantially straight wire into a coiled wire.

[0051] In some embodiments the implant material comprises a shape memory material. In some embodiments the positioning comprises placing the implant such that an inflow opening of the implant is in the anterior chamber of the eye, and an outflow portion of the implant is in Schlemm’s canal of the eye.

[0052] In certain embodiments the method can be done ab interno; in some embodiments the method can be done ab externo.

[0053] Certain embodiments of the invention include a method of forming an implant, comprising introducing a distal end portion of an elongate tube into a body of a mammal; passing a substantially straight, uncoiled wire through the tube; and forming a coiled implant as the wire emerges from the distal end portion of the tube, while the distal end portion is disposed in the body.

[0054] In some embodiments the implant comprises a shape memory material. Preferably, the introducing comprises introducing the distal end portion into an eye of the mammal. In some embodiments the method includes positioning the coiled implant to enhance drainage from the anterior chamber to Schlemm’s canal.

[0055] Certain embodiments of the invention include a system for delivering an implant within the body of a mammal, the system comprising: an elongate tube having a distal end portion configured for insertion into a cavity in the body; a substantially straight, uncoiled wire, sized to pass through the tube, the wire coiling upon emerging from the distal end portion of the tube to form a coiled implant within the body cavity.

[0056] In some embodiments the wire comprises a shape memory material, the wire having a shape memory corresponding to the coiled implant. In certain embodiments an austenite temperature of the shape memory material is less than body temperature of the mammal.

[0057] In some embodiments the tube has an inner diameter that is not substantially greater than an outer diameter of the wire. In some embodiments the substantially straight uncoiled wire is about 1-3 centimeters in length. In certain embodiments, the tube is substantially rigid.

[0058] In a preferred arrangement, the distal end portion of the tube has an outer diameter of no more than 200 μm. In a further preferred arrangement, the distal end portion of the tube has an outer diameter of no more than 150 μm. In a further preferred arrangement, the distal end portion of the tube has an outer diameter of no more than 100 μm. In a further preferred arrangement, the distal end portion of the tube has an outer diameter of no more than 50 μm.

[0059] In some embodiments the coiled implant is about 100-200 μm in diameter. In some embodiments the coiled implant has an angulation along its long axis.

[0060] In certain preferred arrangements, the coiled implant is sized to extend from Schlemm’s canal to the anterior chamber. In certain preferred arrangements, the coiled implant comprises a plurality of coil windings, wherein at least two of the plurality of coil windings are substantially in contact with each other.

[0061] Certain embodiments of the invention include a method for treating glaucoma, comprising surgically placing an implant comprising a wire coil in at least one of Schlemm’s canal and the trabecular meshwork of an eye. In some embodiments the method includes positioning the implant to extend from the anterior chamber of the eye through the trabecular meshwork into Schlemm’s canal.

BRIEF DESCRIPTION OF THE DRAWINGS

[0062] Additional objects and features will become more apparent and the may be best understood from the following
Detailed Description of exemplary embodiments, when read with reference to the accompanying drawings.

[0063] FIG. 1 is a coronal cross-sectional view of an eye for illustration purposes.

[0064] FIG. 2 is an enlarged cross-sectional view of an anterior chamber angle of the eye of FIG. 1.

[0065] FIG. 3 is a simplified partial of an eye illustrating the implantation of a coil wire stent through the trabecular meshwork of an eye.

[0066] FIG. 4A is a first embodiment of a coil wire stent.

[0067] FIG. 4B is a second embodiment of a coil wire stent.

[0068] FIG. 4C is a third embodiment of a coil wire stent.

[0069] FIG. 5 is an applicator having a plurality of coil wire stents at their uncoiled shape.

[0070] FIG. 6 is an applicator with a partially deployed coil wire stent.

[0071] FIG. 7 is another embodiment of the applicator having a plurality of coil wire stents at their coiled shape.

[0072] FIG. 8 is a cross-section view, section I-I of FIG. 7, showing a flattened coil wire stent.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

[0073] Referring to FIGS. 1 to 8, what is shown is a coil wire stent and methods for the treatment of glaucoma by diverting aqueous humor in an eye from the anterior chamber into Schlemm’s canal. In particular, a stent implant is used to bypass diseased or deficient trabecular meshwork at the level of trabecular meshwork to use or restore existing outflow pathways and methods thereof. Some preferred embodiments of the invention described herein relate particularly to surgical and therapeutic treatment of glaucoma through reduction of intraocular pressure. While the description sets forth various embodiment specific details, it will be appreciated that the description is illustrative only and should not be construed in any way as limiting thereto, which may occur to those who are skilled in the art, are also encompassed by the general concepts described herein.

[0074] For background illustration purposes, FIG. 1 shows a sectional view of an eye 10, while FIG. 2 shows a close-up view, showing the relative anatomical locations of the trabecular meshwork, the anterior chamber, and Schlemm’s canal. Thick collagenous tissue known as sclera 11 covers the entire eye 10 except that portion covered by the cornea 12. The cornea 12 is a thin transparent tissue that focuses and transmits light into the eye and the pupil 14, which is the circular hole in the center of the iris 13 (colored portion of the eye). The cornea 12 merges into the sclera 11 at a juncture referred to as the limbus 15. The ciliary body 16 begins internally in the eye and extends along the interior of the sclera 11 and becomes the choroid 17. The choroid 17 is a vascular layer of the eye underlying retina 18. The optic nerve 19 transmits visual information to the brain and is sequentially destroyed by glaucoma.

[0075] The anterior chamber 20 of the eye 10, which is bound anteriorly by the cornea 12 and posteriorly by the iris 13 and lens 26, is filled with aqueous. Aqueous is produced primarily by the ciliary body 16 and reaches the anterior chamber angle 25 formed between the iris 13 and the cornea 12 through the pupil 14. In a normal eye, the aqueous is removed through the trabecular meshwork 21. Aqueous passes through trabecular meshwork 21 into Schlemm’s canal 22 and through the aqueous veins 23, which merge with blood-carrying veins, and into venous circulation. Intraocular pressure of the eye 10 is maintained by the intricate balance of secretion and outflow of the aqueous in the manner described above. Glaucoma is characterized by the excessive buildup of aqueous fluid in the anterior chamber 20, which produces an increase in intraocular pressure (fluids are relatively incompressible and pressure is directed equally to all areas of the eye).

[0076] As shown in FIG. 2, the trabecular meshwork 21 constitutes a small portion of the sclera 11. It is understandable that creating a hole or opening for implanting a device through the tissues of the conjunctiva 24 and sclera 11 is relatively a major surgery as compared to a surgery for implanting a device through the trabecular meshwork 21 only.

[0077] The trabecular meshwork 21 lies in the anterior chamber angle 25, between the scleral spur posteriorly and Schwalbe’s line anteriorly. In cross-section, the trabecular meshwork has a triangular shape, its apex at Schwalbe’s line, and the base formed by the scleral spur and the inner fibers of the ciliary muscle, the inner wall facing the anterior chamber, and the outer wall comprising the inner wall of Schlemm’s canal. The trabecular meshwork consists of three components: the inner uveal meshwork, the central corneoscleral meshwork, and the outer juxtaocular tissue. The inner layers do not provide resistance to aqueous outflow. It consists of a layer of connective tissue lined on either side by endothelium: the outer layer of endothelium is part of Schlemm’s canal and the inner layer is continuous with the trabecular endothelium material. Cellular depopulation and accumulation of extracellular material, appearing as “plaque” in SEM sections, are associated with aging but are accelerated and exaggerated in open-angle glaucoma. The connective tissue has elastic fibers that are connected with tendons of the ciliary muscle. Contraction of the ciliary muscle may increase spaces between the places of the meshwork and reduce resistance to conventional outflow.

[0078] FIG. 3 shows a simplified partial of an eye illustrating the implantation of a coil wire stent 30 through the trabecular meshwork 21 of an eye. The trabecular meshwork comprises little collagenous material and therefore, exerts little compression on the implanted coiled wire stent 30. In one embodiment, at least a portion of the distal zone 37 of the coil wire stent extends along Schlemm’s canal 22 for some distance. The coil portion lying along and within Schlemm’s canal could act to support and dilate the canal and could be less tightly coiled (as compared to the proximal zone 38 within the trabecular meshwork 21) so as to provide aqueous flow through the coil and into collector ducts. Hence, the elongate inner space (the “lumen”) of the coiled wire stent functions like a conduit for aqueous outflow. In some embodiments, an L-shaped coil wire stent is provided comprising a distal portion having at least one terminal aspect sized and shaped to be received within a portion of Schlemm’s canal and a proximal portion having at least one terminal aspect sized and shaped to be received within the anterior chamber of the eye, wherein the coil wire stent
permits fluid communication from the proximal portion in the anterior chamber to the distal portion in Schlemm’s canal.

[0079] FIG. 4A shows a first embodiment of a coil wire stent 30. The first coil wire stent 30 comprises a conical type or various diameter type coil or coil strut 36 that, in one embodiment, a first end section 31 of the coil wire stent 30 is smaller in circumference than that of a second end section 32. The first end section 31 has a first end 33 which functions as the first segment coming out of the stent delivery applicator 61 (shown in FIGS. 5 and 6). In an alternate embodiment, the second end section 32 having a second end 34 may function as the first segment coming out of the stent delivery applicator 61. The “elongate inner space” 35 of a coil wire stent 30 is meant herein to indicate the space bordered by the coils from the first end section 31 extending to the second end section 32. For example, imagine that the coil structure 36 is covered by a continuous flat sheet between the two end sections 31, 32, and hence, the elongate inner space 35 is defined essentially as the enclosure space within the flat sheet. Alternately, consider that the coiled wire forms a stent in the shape of a solid tube (with constant diameter or various diameter along an axial line), which is elongated compared to the wire’s diameter. The stent’s elongate inner space is the inner lumen of that solid tube.

[0080] FIG. 4B shows a second embodiment of a coil wire stent 40 and FIG. 4C shows a third embodiment of a coil wire stent 50. The second coil wire stent 40 has a coil structure with intimate contacting of any two adjacent coil struts or rings. It is also called a “closed coil wire stent”. As disclosed herein, the second coil wire stent 40 may comprise a constant diameter type, a conical type or a various diameter type coil 46. In one embodiment, a first end section 41 of the coil wire stent 40 and the second end section 42 defines the boundary of the elongate inner space 45, functioning as a conduit for aqueous outflow. In one embodiment, either the first end 43 of the first end section 41 or the second end 44 of the second end section 42 may function as the first segment coming out of the stent delivery applicator 61 during stent deployment.

[0081] The third coil wire stent 50 has a coil structure with spaced apart coil struts upon deployment. It is also called an “open coil wire stent”. As disclosed herein, the third coil wire stent 50 may comprise a constant diameter type, a conical type or a various diameter type coil 56 that, in one embodiment, a first end section 51 of the coil wire stent 50 and the second end section 52 defines the boundary of the elongate inner space 55, functioning as a conduit for aqueous outflow. In one embodiment, either the first end 53 of the first end section 51 or the second end 54 of the second end section 52 may function as the first segment coming out of the stent delivery applicator 61.

[0082] FIG. 5 shows an applicator 61 having a plurality of coil wire stents 30 at their uncoiled shape during the stent delivery phase either in an ab interno procedure or in an ab externo procedure. For illustration, the uncoiled wire stent is essentially straight when held in the lumen 64 of the applicator 61. The stent delivery applicator 61 comprises a distal end 62, which, in one embodiment, has self-piercing sharp edge or energy-assisted piercing capability. The applicator 61 also comprises a plunger 63 (or other stent deployment mechanism) with a push-pull mechanism or rod 65 for suitably deploying one stent out of the applicator 61 at a time. In operations, a trabecular stent system to divert aqueous humor in an eye from the anterior chamber into Schlemm’s canal comprises a coil wire stent comprising a distal section having at least one terminal aspect sized and shaped to be received within a portion of Schlemm’s canal 22 and a proximal section having at least one terminal aspect sized and shaped to be received within the anterior chamber 20 of the eye; a delivery applicator having a distal end and a lumen, the delivery applicator being configured to hold the coil wire stent at an essentially uncoiled shape; and wherein the coil wire stent permits fluid communication from the proximal section in the anterior chamber to the distal section in Schlemm’s canal.

[0083] For illustration, FIG. 6 shows an applicator holding a plurality of stents 30A, 30B with a partially deployed coil wire stent 30A. In one embodiment, a first end 33A of the first stent 30A is deployed out of the distal end 62 of the stent delivery apparatus 61. Once the first end section 31A is out of the constraint of the luminal space of the applicator 61, the coil wire stent 30A reassemblly coils to its pre-shape. The coil structure continues to coil as the deployment of the coil wire stent progresses until the second end 34A is completely deployed out of the lumen 64 of the applicator 61. The coil wire stent as deployed is in its pre-shape as shown in FIGS. 4A, 4B or 4C. In some embodiments, the applicator is partially withdrawn from the first implant site and moved to a second implant site. The deployment of a second coil wire stent 30B is performed accordingly. The coil wire stent is sometimes referred to as “stent” herein.

[0084] In the ab externo procedure, the coil wire stent 30 is inserted or injected into Schlemm’s canal 21 with the aid of an applicator or delivery apparatus 61 that creates a small puncture into the eye 10 from the outside. Referring to FIG. 5, the stent 30 is housed in the applicator 61, and pushed out of the applicator 61 once the applicator tip is in position within the trabecular meshwork 21. Since the tissue surrounding the trabecular meshwork 21 is optically opaque, an imaging technique such as ultrasound biomicroscopy (UBM), optical coherence tomography (OCT) or a laser imaging technique is utilized. The imaging provides guidance for the insertion of the applicator tip and the deployment of the stent 30. This technique can be used with a larger variety of coil wire stent embodiments with slight modifications since the trabecular meshwork 21 is punctured from the sclera or cornea side rather than the anterior chamber side in the ab externo insertion.

[0085] In one aspect of the invention, it is provided a method of delivering a coil wire stent through trabecular meshwork of an eye, comprising the steps of: providing a coil wire stent, the coil wire stent being releasably coilable from an essentially straightened, uncoiled shape to a coiled shape configured to have an elongate luminal-like inner space, the coil wire stent being configured to permit aqueous flow in a direction from an anterior chamber to Schlemm’s canal through the elongate inner space; inserting the coil wire stent at the uncoiled, essentially straightened shape inside an applicator; passing the applicator through several tissue into Schlemm’s canal; and deploying the coil wire stent through trabecular meshwork by diverting the tip facing and piercing through the outer wall of the trabecular meshwork with the coil wire stent in the coiled shape. In some embodiments, the step of deploying the coil wire in the
uncoiled, essentially straightened shape to a desired location is by injecting it from an applicator or injector.

[0086] FIG. 7 shows another embodiment of the applicator 71 having a plurality of coil wire stents 50A, 50B at their coiled shape. The stent delivery applicator 71 comprises a distal end 72, which, in one embodiment, has self-piercing sharp edge or energy-assisted piercing capability (such as radiofrequency or ultrasound heating). In one embodiment, the applicator 71 also comprises a plunger (or other stent deployment mechanism) with a push-pull mechanism or rod for suitably deploying one stent out of the applicator 71 at a time. In another embodiment, the applicator 71 comprises a rotatable plunger 73 which is driven by a rotating means 77 mounted at the handle 76 of the applicator 71 with a forward rotating mechanism or rod 75 for suitably deploying one stent out of the applicator 71 at a time by rotatably pushing the stent forward. In operations, the distal end 54 of the distal end section 52 of the distal stent 50A has a sharp edge so as to rotatably pierce through the trabecular meshwork 21. After stent implantation, the proximal end section 51 would stay at about the anterior chamber 20 under an ab interno procedure or would stay at about Schlemm’s canal 22 under an ab externo procedure.

[0087] In some embodiments of the invention, it is provided the use of the coil wire stent that is not deformed when placed within the applicator, wherein the stent is rotatable when being deployed out of the applicator. In one embodiment, the step of deployment is carried out by using a rotating plunger to essentially screw the stent through the meshwork and using the rotary motion to help self-guide the stent along Schlemm’s canal.

[0088] FIG. 8 shows a cross-section view, section I-I of FIG. 7, showing a flattened coil wire stent 50C within the applicator 71. In some embodiments of the invention, it is provided a coil wire stent that is formable when loaded into the applicator (also known as inserter), such that the coil configuration still exists but the coil struts are all lying along the axis (its appearance would be that of a spring that has been stepped on) with the inserter needle having an oval or non-round cross-section so as to reduce the incision size required. In one embodiment, regarding the insertion of the stent into the trabecular meshwork, the applicator tip could be stopped prior to penetrating the meshwork, allowing the wire of the stent to penetrate the meshwork and form a lumen as it coils.

[0089] In some embodiments, the coil wire stent is self-coiling. In other words, the stent recoils after removing the constraint. In some embodiments, the coil wire stent is made of a shape memory material that is coilably preshaped so as to become coiled after being delivered out of the applicator when the stent is heated to above the shape transitional temperature.

[0090] Fiber-coupled laser light is one choice for remote delivery of energy. By way of example, an 800-nm 1.5-W laser (Spectra-Physics Semiconductor Laser Div, Tucson, Az) is used as the heat source. The shape memory stent may be impregnated with indocyanine green or trypan blue for visual observation using a goniolens. The optic fiber is chemically treated to remove the cladding of the fiber at the stent-contacting region, whereas the stent-contacting region is roughened with a high-index adhesive. Light leaks from the fiber core to the high-index adhesive, and then out to the shape memory stent.

[0091] In another aspect, the coil wire stent made of shape memory material is deployed out of the applicator in an essentially straightened, uncoiled shape into Schlemm’s canal, followed by a step of first heating the middle portion to above the shape transitional temperature to initiate the recoiling process at the middle section.

[0092] In another aspect, the shape memory material is a shape memory alloy of nickel-titanium alloy (such as Nitinol) or copper-based shape memory alloy (such as CuZnAl or CuAlNi), or a shape memory polymer. The shape-transition temperature for the shape-memory Nitinol or plastic is preferably between about 30° C. and about 45° C. The shape-transition temperature is more preferably between about 35° C. and 40° C. so as to minimize tissue damage.

[0093] In some embodiments, the coil wire stent is made of an elastic material that is coilably preshaped so as to become coiled after being delivered out of the applicator when the constraint from the applicator is released. Examples for elastic material include silicone, polyurethane, rubber, polyvinyl pyrrolidone, fluorinated elastomer, superelastic Nitinol, or the like. Superelasticity refers to the unusual ability of certain material to undergo large elastic deformation. While many metals exhibit superelastic effects, only Ni—Ti based alloys appear to be chemically and biologically compatible with the human body. The preferred binary Ni—Ti alloys showing superelasticity is the one containing between 50.6 and 51.0 atomic percent nickel.

[0094] In some embodiments, the coil wire stent is made of at least one nanospring that is coilably preshaped so as to become coiled after being delivered out of the applicator when the constraint from the applicator is removed. Characteristics for nanosprings include helical shapes formed from long single crystals of zinc oxide that possess piezoelectric and electrostatic polarization properties. Typically, the nanosprings are up to several millimeters long, 10-60 nm wide, and 5-20 nm thick. A coil wire stent may comprise multiple nanosprings that are deployable from a stent applicator. In one embodiment, at least one end of the multiple nanosprings is secured together to form coil wire stent of the invention.

[0095] In some embodiments, the coil wire stent comprises a tip at its distal end, wherein the tip is sized and configured to exert a forceatraumatic to the surrounding tissue. Examples for an atraumatic tip include a blunt tip, a tip with a small loop or ball, or the like without a sharp end.

[0096] In some embodiments, the cross-sectional configuration of the coil strut is not round, preferably in an oval or kidney shape.

[0097] In some embodiments, the coil wire stent comprises a plurality of sections, each section comprising varying properties in loop cross-sectional configuration, strut cross-sectional configuration, loop diameter, strut diameter, strength, material composition, conductivity, shape transitional temperature, and like.

[0098] In some embodiments, the coil wire stent comprises a broad scope of non-straight wire stents, such as a zigzag shape, a random shape, an irregular shape, a shape with crossing-over wires or the like.

[0099] In one embodiment, the stent implant may comprise a biocompatible material, such as a medical grade
stainless steel, Nitinol, high strength metallic wire, spring Nitinol, BTR alloy (these are binary nickel titanium alloys having body temperature response properties specifically developed for deformation in martensitic state close to ambient temperatures. A deformed BTR alloy will recover its original shape and become superelastic when placed inside the human body at 37° C, supplied by Menry Corp. Bethel, Conn.), alloy of biocompatible material, shape memory polymer, biodegradable shape memory material, and the like. In a further alternate embodiment, a composite biocompatible material by surface coating the above-mentioned biomaterial may be used, wherein the coating material may be selected from the group consisting of polytetrafluoroethylene (PTFE), polyimide, hydrogel, hydrophilic substance, heparin, and therapeutic drugs (anti-glaucoma drugs, anti-inflammation drugs, optical nerve protection drugs, anti-angiogenic drugs, and the like).

A drug may be coated or loaded onto the stent and slowly released to the surrounding tissue effective to treat glaucoma and/or other ophthalmology abnormalities. As is well known in the art, a device coated or loaded with a slow-release drug can have prolonged effects on local tissue surrounding the device. The slow-release delivery can be designed such that an effective amount of drug is released over a desired duration.

In one embodiment, the injectable coil wire stent is made of a biodegradable polymer or a biodegradable shape memory polymer. The stent is designed and configured to maintain the lumen-like opening after substantial scar is formed around the opening, but not blocking the opening, and polymer biodegradation is initiated thereafter. In another embodiment, drug may be loaded onto the stent by physically mixing with the biodegradable polymer (shape memory and non shape memory), and the stent is configured for polymer biodegradation at a rate with pharmaceutically acceptable sufficient drug release to the tissue. Therefore, when the stent is biodegraded, drug is released to treat the tissue of trabecular meshwork and/or Schlemm’s canal.

Representative natural biodegradable polymer include polysaccharides such as alginate, dextran, cellulose, collagen, and chemical derivatives thereof (substitutions, additions of chemical groups, for example, alkyl, alkylene, hydroxylations, oxidations, and other modifications routinely made by those skilled in the art), and proteins such as albumin, zein and copolymers and blends thereof, alone or in combination with synthetic polymers. Representative synthetic degradable polymer segments or polymers include polyhydroxy acids, such as poly lactides, polyglycolides and copolymers thereof; poly(ethylene terephthalate); poly(hydroxybutyric acid); poly(hydroxyvaleric acid); poly(lactide-co-e-caprolactone); poly(glycolide-co-e-caprolactone); polycarbonates, poly(pseudo amino acids); poly(amine acids); poly(hydroxyalkanoates); polyoxyhydrates, polylactide esters; and blends and copolymers thereof.

Other suitable polymeric materials for use in the invention include polymers and copolymers of carboxylic acids such as glycolic acid and lactic acid, polypeptides, polysteres such as poly(ethylene terephthalate), polyanhydrides such as nylon, polyacrylonitriles, polyphosphazines, polylactones such as polycaprolactone, and poly(anhydrides such as poly[bis(p-carboxyphenoxy)propylene anhydride] and other polymers or copolymers such as polyethylene, polyvinyl chloride and ethylene vinyl acetate. Other biodegradable polymers could also be used either singly or in combination, or such as homopolymers and copolymers of delta-valerolactone, and p-dioxanone as well as their copolymers with caprolactone. Further, with specific degradation characteristics to provide sufficient lifspan for the particular application. As noted above, a three to six month lifespan may generally be sufficient for use in maintaining openness; shorter or longer periods may be appropriate for other therapeutic applications.

In one embodiment, the stent may comprise a polymer film functioning as drug containing release device whereby the polymer film may be coupled or secured to the stent. The polymer films may be designed to permit the controlled release of the drug at a chosen rate and for a selected duration, which may also be episodic or periodic. Such polymer films may be synthesized such that the drug is bound to the surface or resides within a pore in the film so that the drug is relatively protected from enzymatic attack. The polymer films may also be modified to alter their hydrophilicity, hydrophobicity and vulnerability to platelet adhesion and enzymatic attack.

The stent or device may be used for a direct release of pharmaceutical preparations into ocular tissues. As discussed above, the pharmaceuticals may be compounded within the device or form a coating on the device. Any known drug therapy for glaucoma and/or ophthalmology diseases may be utilized.

As described in the specification, the stent implant may have a length between about 0.2 mm to over a centimeter, depending on the body cavity where the stent implant applies. The outside circumferential diameter of the stent implant may range from about 30 μm to above 500 μm. The “elongate inner space” lumen diameter is preferably in the range between about 10 μm to about 150 μm or larger. The wire of the coil wire stent implant may have a diameter of about 0.1 micron to about 100 microns, preferably about 10 to 50 microns.

In an exemplary embodiment of the trabecular meshwork surgery, the patient is placed in the supine position, prepped, draped and anesthesia obtained. In one embodiment, a small (less than 1 mm in a “Sub one” surgery, or preferably less than 0.5 mm diameter hole) self-sealing incision is made. Through the cornea opposite the stent placement site, an incision is made in trabecular meshwork with the applicator and methods of use. The stent is then advanced through the cornea incision across the anterior chamber held in an applicator under gonioscopic (lens) or endoscopic guidance. The applicator or delivery apparatus is withdrawn and the surgery concludes. The apparatus or the irrigating apparatus may be within a size range from 20 gauges to 40 or higher gauges, preferably about 30-40 gauges. A 35-gauge tube is 0.003 inch in outer diameter with a 0.002-inch inner diameter and would be very flexible that is characterized with slightly stiffer than a human hair.

In one aspect of the invention, an ab interno method for delivering a stent within an eye is disclosed, comprising providing an elongate applicator having a stent at the distal section and a piercing member at the distal end, advancing the distal end of the applicator with the piercing member through at least a portion of the trabecular mesh-
work of the eye, advancing (or a first phase of “injecting”) the stent along the applicator toward the distal end, injecting (or a second phase of “injecting”) and coailably positioning the stent to conduct aqueous humor between the anterior chamber of the eye and Schlemm’s canal, and retrieving the piercing member. In a preferred embodiment, the applicator does not pass through a portion of the trabecular meshwork; instead, the applicator bypasses around the trabecular meshwork.

[0109] In another aspect of the invention, an ab externo method for delivering a stent within an eye is disclosed, comprising providing an elongate applicator having a stent at the distal section and a piercing member at the distal end, advancing the distal end of the applicator with the piercing member from cornea through at least a portion of Schlemm’s canal of the eye, advancing (or a first phase of “injecting”) the stent along the applicator toward the distal end, injecting (or a second phase of “injecting”) and coailably positioning the stent for one end inside the anterior chamber and at least a portion of the other end inside Schlemm’s canal so as to conduct aqueous humor between the anterior chamber of the eye and Schlemm’s canal, and retrieving the piercing member and the applicator. In an alternate embodiment, the applicator does not pass through a portion of the trabecular meshwork; instead, the applicator bypasses around the trabecular meshwork into a collector duct or episcleral vein.

[0110] In some embodiments of the invention, it is disclosed a method of delivering a coil wire stent through trabecular meshwork of an eye, comprising the steps of: providing a coil wire stent, the coil wire stent being releasably coilable from an essentially straightened, uncoiled shape to a coiled shape configured to have an elongate luminal-like inner space, the coil wire stent being configured to permit aqueous flow in a direction from an anterior chamber to Schlemm’s canal through the elongate inner space, inserting the coil wire stent at the uncoiled, essentially straightened shape inside an applicator; passing the applicator through at least a portion of the trabecular meshwork; and deploying the coil wire stent to a desired location with the coil wire stent in the coiled shape.

[0111] In some embodiments, the step of passing the applicator is guided with a pre-deployed guidewire into trabecular meshwork and/or Schlemm’s canal. A guidewire is deployed to provide a route for the coil wire stent to follow. The guidewire is inserted through trabecular meshwork between the anterior chamber and Schlemm’s canal. Therefore, the deployed coiled wire tends to follow along the guidewire. Thereafter, the guidewire is retracted and removed from the patient.

[0112] In some embodiments, the step of deploying the coil wire stent is carried out by retracting the applicator so that the deployed stent is stationary relative to the surrounding tissue axially.

[0113] In certain embodiments, the advancing of the applicator comprises advancing it from the anterior chamber into the trabecular meshwork. In further embodiments, the positioning comprises positioning an end of the stent within Schlemm’s canal adjacent to an aqueous collection channel.

[0114] In further preferred embodiments, an apparatus for delivering a stent in an eye comprises an elongate applicator member adapted for insertion into an anterior chamber of the eye, the elongate member having a distal end section configured to retain the stent therein, the distal end section comprising a piercing member configured to form an opening in the trabecular meshwork of the eye for receipt of the stent, such that at least a portion of one end of the stent is in Schlemm’s canal. The elongate applicator member can further comprise a lumen that conducts fluid toward the distal end section.

[0115] The preferred embodiment provides further surgical treatment of glaucoma (trabecular bypass surgery) at the level of trabecular meshwork or around bypassing the trabecular meshwork and restores existing physiological outflow pathways. An implant bypasses diseased trabecular meshwork at the level of trabecular meshwork, and which restores existing physiological outflow pathways. The implant has an inlet end, an outlet end and a lumen between the inlet end and the outlet end. The inlet is positioned in the anterior chamber at about the level of the internal surface of the trabecular meshwork and the outlet end is positioned at about the external surface of the diseased trabecular meshwork and/or into fluid collection channels of the existing outflow pathways.

[0116] In accordance with a preferred method, trabecular bypass surgery creates an opening or a hole through the diseased trabecular meshwork through minor microsurgery in a one step “injectable stent” procedure. To prevent “filling in” of the hole, a biocompatible coil wire stent is placed within the hole as a stent. In one exemplary embodiment, the stent implant may be positioned across the diseased trabecular meshwork alone and it does not extend into the eye wall or sclera. In another embodiment, the inlet end of the implant is exposed to the anterior chamber of the eye while the outlet end is positioned at the exterior surface of the trabecular meshwork. In another exemplary embodiment, the outlet end is positioned at and over the exterior surface of the trabecular meshwork and into the fluid collection channels of the existing outflow pathways. In still another embodiment, a portion of the outlet end is positioned in the Schlemm’s canal. In an alternative embodiment, the outlet end enters into fluid collection channels up to the level of the aqueous veins or episcleral aqueous veins.

[0117] One of the advantages of trabecular bypass surgery, as disclosed herein, and the use of a stent implant to bypass diseased trabecular meshwork at the level of trabecular meshwork and thereby use existing outflow pathways is that the treatment of glaucoma is substantially simpler than in existing therapies. A further advantage of the invention is the utilization of simple microsurgery that may be performed on an outpatient basis with rapid visual recovery and greatly decreased morbidity. Finally, a distinctly different approach is used than is found in existing implants. Physiological outflow mechanisms are used or re-established by the implant of the invention, in contradistinction with previously disclosed methodologies.

[0118] Some embodiments provide a glaucoma stent to be inserted through an opening of the deficient trabecular meshwork, wherein the opening is created by using a cutting instrument slid inside a lumen of the glaucoma stent in a combined one-step cutting and implanting inserting operation.

[0119] Furthermore, some embodiments of the invention relate to a method of stenting a body channel, conduit, or
opening (collectively called a “cavity”) by delivering a coil wire stent of the invention to the cavity, comprising the steps of: delivering a coil wire stent, the coil wire stent being releasably coilable from an essentially straightened, uncoiled shape to a partially or completely coiled shape configured to have an elongate luminal-like inner space; inserting the coil wire stent at the uncoiled, essentially straightened shape inside an applicator, cannula, injector, or catheter; passing the applicator through at least a portion of the body cavity; and deploying the coil wire stent to a desired location with the coil wire stent in the coiled shape.

[0120] In some embodiments, the body cavity is selected from a group consisting of vascular vessels, arteries, veins, capillaries, trachea, esophagus, uterus, ureter, Fallopian tubes, urethra, intestines, colon, and the like.

[0121] As used herein, the terms “wire” and “wire coil” are not meant to connote that the stent or implant is or must be metallic. Rather, the wire embodiments described herein may be made of one or more of any of various materials, including metals or plastics.

[0122] From the foregoing description, it should now be appreciated that a novel coil wire stent and methods of use in either an ab interno or ab externo approach for surgical treatment of glaucoma has been disclosed for releasing excessive intraocular pressure. While the invention has been described with reference to a specific embodiment, the description is illustrative of the invention and is not to be construed as limiting the invention. Various modifications and applications may occur to those who are skilled in the art, without departing from the true spirit and scope of the invention, as described by the appended claims.

What is claimed is:

1. A method of treating glaucoma, comprising:
   introducing an implant material through an opening in an eye;
   modifying a configuration of the implant material within the eye to form an implant having a different configuration;
   positioning the implant to enhance drainage from the anterior chamber of the eye to Schlemm’s canal of the eye.
2. The method in claim 1, wherein the implant has a diameter substantially greater than the diameter of the opening.
3. The method in claim 1, wherein the modifying comprises converting a substantially straight wire into a coiled wire.
4. The method in claim 1, wherein implant material comprises a shape memory material.
5. The method in claim 1, wherein the positioning comprises placing the implant such that an inflow opening of the implant is in the anterior chamber of the eye, and an outflow portion of the implant is in Schlemm’s canal of the eye.
6. A method of forming an implant within an eye, the method comprising:
   introducing a distal end portion of an elongate tube into said eye;
   forming a coiled implant as the wire emerges from the distal end portion of the tube, while the distal end portion is disposed in the eye.
7. The method of claim 6, wherein the implant comprises a shape memory material.
8. The method of claim 6, further comprising positioning the coiled implant to enhance drainage from the anterior chamber to Schlemm’s canal.
9. A method for treating glaucoma, comprising surgically placing an implant comprising a wire coil in at least one of Schlemm’s canal and the trabecular meshwork of an eye.
10. The method in claim 9, further comprising positioning said implant to extend from the anterior chamber of the eye through the trabecular meshwork into Schlemm’s canal.
11. A system for delivering an implant within an eye of a mammal, the system comprising:
   an elongate tube having a distal end portion configured for insertion into said eye;
   a substantially straight, uncoiled wire, sized to pass through the tube, said wire coiling upon emerging from the distal end portion of the tube to form a coiled implant within said eye.
12. The system of claim 11, wherein the wire comprises a shape memory material, said wire having a shape memory corresponding to said coiled implant.
13. The method of claim 12, wherein an austenite-temperature of the shape memory material is less than body temperature of the mammal.
14. The system of claim 11, wherein the tube has an inner diameter that is not substantially greater than an outer diameter of the wire.
15. The system of claim 11, wherein the substantially straight uncoiled wire is about 1-3 centimeters in length.
16. The system of claim 11, wherein the tube is substantially rigid.
17. The system of claim 11, wherein the distal end portion of the tube has an outer diameter of no more than 200 μm.
18. The system of claim 17, wherein the distal end portion of the tube has an outer diameter of no more than 150 μm.
19. The system of claim 18, wherein the distal end portion of the tube has an outer diameter of no more than 100 μm.
20. The system of claim 19, wherein the distal end portion of the tube has an outer diameter of no more than 50 μm.
21. The system of claim 11, wherein the coiled implant is about 100-200 μm in diameter.
22. The system in claim 11, wherein the coiled implant has an angulation along its long axis.
23. The system in claim 11, wherein the coiled implant is sized to extend from Schlemm’s canal to the anterior chamber.
24. The system in claim 11, further comprising a plurality of coil windings of the coiled implant, wherein at least two windings of said plurality of coil windings are substantially in contact with each other.

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