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(54) Titre : APPAREIL ET METHODE DE TRAITEMENT DE MALADIES OCCULAIRES
(54) Title: APPARATUS AND METHOD FOR TREATING AN OCULAR DISORDER

(57) Abrégé/Abstract:
An implant for treating an ocular disorder comprises am inlet portion configured to extend through a portion of a trabecular meshwork of an eye, and an outlet portion configured to extend into Schlemm's canal of the eye. The outlet portion has at least one protrusion configured to exert traction against an inner surface of Schlemm's canal and the protrusion extends from the implant in a direction substantially perpendicular to a long axis of Schlemm's canal.

Abstract of the Invention

An implant for treating an ocular disorder comprises an inlet portion configured to extend through a portion of a trabecular meshwork of an eye, and an outlet portion configured to extend into Schlemm's canal of the eye. The outlet portion has at least one protrusion configured to exert traction against an inner surface of Schlemm's canal and the protrusion extends from the implant in a direction substantially perpendicular to a long axis of Schlemm's canal.

APPARATUS AND METHOD FOR TREATING AN OCULAR DISORDER

This application is divided from Canadian Patent Application Serial Number 2,404,037 filed March 8, 2001.

Field of the Invention

The present invention generally relates to improved medical devices and methods for the reduction of elevated pressure in organs of the human body. More particularly, the present invention relates to the treatment of glaucoma by trabecular bypass surgery, which is a means for using an implant or seton, such as a micro stent, shunt or the like, to bypass diseased trabecular meshwork at the level of trabecular meshwork and use/ restore existing outflow pathways.

Background of the Invention

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.

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 (juxtacanilicular meshwork).

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 which may include edema or swelling of the trabecular spaces (from steroid use), abnormal pigment dispersion, or diseases such as hyperthyroidism that produce vascular congestion.

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 which is most widely used and is augmented with topically applied anticancer drugs such as 5-flurouracil or mitomycin-c to decrease scarring and increase surgical success.

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).

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.

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

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.

Trabeculopuncture: Q-switched Neodymiun (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.

Goniophotoablation/Laser Trabecular Ablation: Goniophotoablation 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.

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

Although trabeculectomy is the most commonly performed filtering surgery, *Viscocanulostomy* (VC) and *non-penetrating trabeculectomy* (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 canulated and viscoelastic substance 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.

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.

Examples of implantable shunts or devices for maintaining an opening for the release of aqueous humor from the anterior chamber of the eye to the sclera or space underneath conjunctiva have been disclosed in U.S. Pat. Nos. 6,007,511 (Prywes), 6,007,510 (Nigam), 5,893,837 (Eagles et al.), 5,882,327 (Jacob), 5,879,319 (Pynson et al.), 5,807,302 (Wandel), 5,752,928 (de Roulhac et al.), 5,743,868 (Brown et al.), 5,704,907 (Nordquist et al.), 5,626,559 (Solomon), 5,626,558 (Suson), 5,601,094 (Reiss), RE. 35,390 (Smith), 5,558,630 (Fisher), 5,558,629 (Baerveldt et al.), 5,520,631 (Nordquist et al.), 5,476,445 (Baerveldt et al.), 5,454,796 (Krupin), 5,433,701 (Rubinstein), 5,397,300 (Baerveldt et al.), 5,372,577 (Ungerleider), 5,370,607 (Memmen), 5,338,291 (Speckman et al.), 5,300,020 (L'Esperance, Jr.), 5,178;604 (Baerveldt et al.), 5,171,213 (Price, Jr.), 5,041,081 (Odrich), 4,968,296 (Ritch et al.), 4,936,825 (Ungerleider), 4,886,488 (White), 4,750,901 (Molteno), 4,634,418 (Binder), 4,604,087 (Joseph), 4,554,918 (White), 4,521,210 (Wong), 4,428,746 (Mendez), 4,402,681 (Haas et al.), 4,175,563 (Arenberg et al.), and 4,037,604 (Newkirk).

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.

The trabecular meshwork and juxtacanilicular 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.

Therefore, there is a great clinical need for the treatment of glaucoma by a method that would be faster, safer and less expensive than currently available modalities. Trabecular bypass surgery is an innovative surgery which uses a micro stent, shunt, or other implant to bypass diseased trabecular meshwork alone at the level of trabecular meshwork and use or restore existing outflow pathways. The object of the present invention is to provide a means and methods for treating elevated intraocular pressure in a manner which is simple, effective, disease site specific and can be performed on an outpatient basis.

Summary of the Invention

In some preferred embodiments, the present invention provides an implant for treating an ocular disorder, comprising: an inlet portion configured to extend through a portion of a trabecular meshwork of an eye; and an outlet portion configured to extend into Schlemm's canal of said eye; wherein the outlet portion has at least one protrusion configured to exert traction against an inner surface of Schlemm's canal, the protrusion extending from the implant in a direction substantially perpendicular to a long axis of Schlemm's canal.

The present invention also provides an implant for treating an ocular disorder, comprising: an inlet portion configured to extend through a portion of a trabecular meshwork of an eye; an outlet portion configured to extend into and along Schlemm's canal of the eye; wherein the implant provides a flow path between an anterior chamber of the eye and Schlemm's canal, and wherein said implant has a retention protrusion configured to anchor the implant and stabilize at least a portion of the flow path through the implant.

The present invention also provides an implant for treating an ocular disorder, comprising: a body having an inlet section, an outlet section, a lumen extending between the inlet section and the outlet section, wherein the body has a longitudinal axis, wherein the inlet section is configured to be positioned in an anterior chamber of an eye, and wherein the outlet section is configured to be positioned into an existing outflow pathway of the eye and the outlet section comprise a ridge protruding generally radially outwardly relative to the longitudinal axis of the body.

The present invention also provides an ocular implant, comprising: a body having a first end portion configured to be positioned in an anterior chamber of an eye when implanted, the first end portion comprising at least one inlet opening and having a first axis defined therethrough, and a second end portion configured to be positioned in a physiologic outflow pathway of the eye when implanted, the second end portion comprising at least one outlet opening and having a second axis defined therethrough, wherein the at least one inlet opening and the at least one outlet opening are in fluid communication; an anchor disposed on the second end portion

configured to be positioned in the physiologic outflow pathway and extending substantially perpendicularly to the second axis without extending beyond the physiologic outflow pathway; and a therapeutic agent.

The present invention also provides an implant for treating an ocular disorder, comprising: a body having a first end and a second end and a fluid flow path defined between at least one inlet and one outlet, said body including at least two regions each having a cross-sectional size smaller than adjacent regions on the implant, said at least two regions being disposed remote from the second end between at least some of the inlets and outlets, said body configured to conduct fluid from an anterior chamber of an eye to a physiologic outflow pathway of the eye, wherein said second end is sized and shaped to be inserted into and along a portion of a length of the physiologic outflow pathway of the eye, and wherein said second end is tapered.

The present invention also provides an implant for treating an ocular disorder, comprising: an elongated body having an inlet end and an outlet end, the elongated body configured to extend through a tissue of an eye such that the inlet end resides in an anterior chamber of the eye and the outlet end resides in and along a portion of a length of a physiologic outflow pathway of the eye; and an inner lumen within the elongated body, the lumen having an inlet port and an outlet port for providing a fluid flow pathway through the elongated body; wherein the elongated body comprises at least two regions each having a cross-sectional dimension greater than adjacent regions of the elongated body, said at least two regions disposed remotely of said outlet end; and wherein said outlet end is tapered.

The present invention also provides an implant for treating an ocular disorder, comprising: a body of biocompatible material sized and shaped to facilitate the transport of aqueous humor from an anterior chamber of an eye to and within Schlemm's canal of the eye, the body comprising first and second lumens, each of which bypasses a trabecular meshwork of the eye and terminates in Schlemm's canal, so as to receive aqueous humor from the anterior chamber and transport said aqueous humor into Schlemm's canal.

The present invention also provides a system for treating an ocular disorder, comprising: a delivery device, the delivery device comprising a handpiece and an elongate delivery member; and an ophthalmic drainage implant which, following implantation at an implantation site, conducts fluid from an anterior chamber of an eye to an outflow pathway of the eye, the implant comprising: a body having a proximal section and a distal section with respect to the handpiece of the delivery device, the proximal section comprising an inlet and the distal section comprising at least one outlet, the body having a maximum cross-sectional dimension sized to allow insertion of the body through a self-sealing opening in the eye to access the anterior chamber; and a lumen extending through the body from the inlet of the proximal section to the at least one outlet of the distal section, the lumen defining a wall thickness of the body; wherein a distal end of the distal section of the body is tapered; wherein at least a portion of the lumen of the ophthalmic drainage implant receives at least a portion of the elongate delivery member in an orientation such that the distal section leads the proximal section; wherein

the elongate delivery member is configured for ab interno insertion of the ophthalmic drainage implant through the self-sealing incision and sized to extend across the anterior chamber; and wherein the ophthalmic drainage implant has sufficient length between the proximal section and distal section such that, upon implantation, at least a portion of the proximal section of the ophthalmic drainage implant is disposed within the anterior chamber and at least a portion of the distal section of the ophthalmic drainage implant extends into and along a portion of the outflow pathway of the eye.

The present invention also provides a system for treating an ocular disorder, comprising: a delivery device comprising a guidewire, the guidewire having a distal end adapted to form an opening in ocular tissue; and an elongated implant comprising an inlet section, an outlet section, and a lumen therebetween, wherein the implant is configured to be advanced over the guidewire and introduced into the opening formed in the ocular tissue by the guidewire.

The present invention also provides an ocular implant, comprising: a body comprising a biocompatible material and a therapeutic drug; the body having an inlet portion and an outlet portion; the inlet portion being configured to reside in an anterior chamber of an eye; the outlet portion being sized and shaped to be disposed in a physiologic outflow pathway of the eye when the inlet portion is in the anterior chamber; and the outlet portion having an outflow opening such that the body drains fluid from the anterior chamber to the physiologic outflow pathway.

One of the advantages of trabecular bypass surgery, as disclosed herein, and the use of a seton 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 present invention, in contradistinction with previously disclosed methodologies.

Brief Description of the Drawings

Additional objects and features of the present invention will become more apparent and the invention itself will be best understood from the following Detailed Description of Exemplary Embodiments, when read with reference to the accompanying drawings.

FIG. 1 is a sectional view of an eye for illustration purposes.

FIG. 2 is a close-up sectional view, showing the anatomical diagram of trabecular meshwork and the anterior chamber of the eye.

FIG. 3 is an embodiment of the seton implant constructed according to the principles of the invention.

FIG. 4 is a top cross-sectional view of section 1-1 of FIG. 3.

FIG. 5 is another embodiment of the seton implant constructed in accordance with the principles of the invention.

FIG. 6 is a perspective view illustrating the seton implant of the present invention positioned within the tissue of an eye.

FIG. 7 is an alternate exemplary method for placing a seton implant at the implant site.

Detailed Description of the Preferred Embodiment

Referring to FIGS. 1 to 7, what is shown is a method for the treatment of glaucoma by trabecular bypass surgery. In particular, a seton implant is used to bypass diseased trabecular meshwork at the level of trabecular meshwork to use or restore existing outflow pathways and methods thereof.

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.

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).

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. A seton implant **31** of the present invention for either using or restoring existing outflow pathways positioned through the trabecular meshwork **21** is illustrated in FIG. 5.

In a first embodiment, a method for increasing aqueous humor outflow in an eye of a patient to reduce the intraocular pressure therein. The method comprises bypassing diseased trabecular meshwork at the level of the trabecular meshwork and thereby restoring existing outflow pathways. Alternately, a method for increasing aqueous humor outflow in an eye of a patient to reduce an intraocular pressure therein is disclosed. The method comprises bypassing diseased trabecular meshwork at a level of said trabecular meshwork with a seton implant and using existing outflow pathways. The seton implant **31** may be an elongated seton or other appropriate shape, size or configuration. In one embodiment of an elongated seton implant, the seton has an inlet end, an outlet end and a lumen therebetween, wherein the inlet end is positioned at an anterior chamber of the eye and the outlet end is positioned at about an exterior surface of said diseased trabecular meshwork. Furthermore, the outlet end may be positioned into fluid collection channels of the existing outflow pathways. Optionally, the existing outflow pathways may comprise Schlemm's canal **22**. The outlet end may be further positioned into fluid collection channels up to the level of the aqueous veins with the seton inserted either in a retrograde or antegrade fashion with respect to the existing outflow *pathways.*

In a further alternate embodiment, a method is disclosed for increasing aqueous humor outflow in an eye of a patient to reduce an intraocular pressure therein. The method comprises (a) creating an opening in trabecular meshwork, wherein the trabecular meshwork comprises an interior side and exterior side; (b) inserting a seton implant into the opening; and (c) transporting the aqueous humor by said seton implant to bypass the trabecular meshwork at the level of said trabecular meshwork from the interior side to the exterior side of the trabecular meshwork.

FIG. 3 shows an embodiment of the seton implant **31** constructed according to the principles of the invention. The seton implant may comprise a biocompatible material, such as a medical grade silicone, for example, the material sold under the trademark Silastic™, which is available from Dow Corning Corporation of Midland, Michigan, or polyurethane, which is sold under the trademark Pellethane™, which is also available from Dow Corning Corporation. In an alternate embodiment, other biocompatible materials (biomaterials) may be used, such as polyvinyl alcohol, polyvinyl pyrolidone, collagen, heparinized collagen, tetrafluoroethylene, fluorinated polymer, fluorinated elastomer, flexible fused silica, polyolefin, polyester, polysilison, mixture of biocompatible materials, 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 polytetrafluoroethlyene (PTFE), polyimide, hydrogel, heparin, therapeutic drugs, and the like.

The main purpose of the seton implant is to assist in facilitating the outflow of aqueous in an outward direction **40** into the Schlemm's canal and subsequently into the aqueous collectors and the aqueous veins so that the intraocular pressure is balanced. In one embodiment, the seton implant **31** comprises an elongated tubular element having a distal section **32** and an inlet section **44**. A rigid or flexible distal section **32** is positioned inside one of the existing outflow pathways. The distal section may have either a tapered outlet end **33** or have at least one ridge **37** or other retention device protruding radially outwardly for stabilizing the seton implant inside said existing outflow pathways after implantation. For stabilization purposes, the outer surface of the distal section **32** may comprise a stubbed surface, a ribbed surface, a surface with pillars, a textured surface, or the like. The outer surface **36**, including the outer region **35** and inner region **34** at the outlet end **33**, of the seton implant is biocompatible and tissue compatible so that the interaction/irritation between the outer surface and the surrounding tissue is minimized. The seton implant may comprise at least one opening at a location proximal the distal section **32**, away from the outlet end **33**, to allow flow of aqueous in more than one direction. The at least one opening may be located on the distal section **32** at about opposite of the outlet end **33**.

In another exemplary embodiment, the seton implant **31** may have a one-way flow controlling means **39** for allowing one-way aqueous flow **40**. The one-way flow controlling means **39** may be selected from the group consisting of a check valve, a slit valve, a micropump, a semi-permeable membrane, or the like. To enhance the outflow efficiency, at least one optional opening **41** in the proximal portion of the distal section **32**, at a location away from the outlet end **33**, and in an exemplary embodiment at the opposite end of the outlet end **33**, is provided.

FIG. 4 shows a top cross-sectional view of FIG. 3. The shape of the opening of the outlet end **33** and the remaining body of the distal section **32** may be oval, round or some other shape adapted to conform to the shape of the existing outflow pathways. This configuration will match the contour of Schlemm's canal to stabilize the inlet section with respect to the iris and cornea by preventing rotation.

As shown in FIG. 3, the seton implant of the present invention may have a length between about 0.5 mm to over a meter, depending on the body cavity the seton implant applies to. The outside diameter of the seton implant may range from about 30 μm to about 500 μm. The lumen diameter is preferably in the range between about 20 μm

to about 150 μm. The seton implant may have a plurality of lumens to facilitate multiple flow transportation. The distal section may be curved at an angle between about 30 degrees to about 150 degrees, in an exemplary embodiment at around 70-110 degrees, with reference to the inlet section **44**.

FIG. 5 shows another embodiment of the seton implant **45** constructed in accordance with the principles of the invention. In an exemplary embodiment, the seton implant **45** may comprise at least two sections: an inlet section **47** and an outlet section **46**. The outlet section has an outlet opening 48 that is at the outlet end of the seton implant **45**. The shape of the outlet opening **48** is preferably an oval shape to conform to the contour of the existing outflow pathways. A portion of the inlet section **47** adjacent the joint region to the outlet section **46** will be positioned essentially through the diseased trabecular meshwork while the remainder of the inlet section **47** and the outlet section **46** are outside the trabecular meshwork. As shown in FIG. 5, the long axis of the oval shape opening **48** lies in a first plane formed by an X-axis and a Y-axis. To better conform to the anatomical contour of the anterior chamber **20**, the trabecular meshwork **21** and the existing outflow pathways, the inlet section **47** may preferably lie at an elevated second plane, at an angle θ, from the first plane formed by an imaginary inlet section **47A** and the outlet section **46**. The angle θ may be between about 30 degrees and about 150 degrees.

FIG. 6 shows a perspective view illustrating the seton implant **31, 45** of the present invention positioned within the tissue of an eye **10**. A hole/opening is created through the diseased trabecular meshwork **21**. The distal section **32** of the seton implant **31** is inserted into the hole, wherein the inlet end **38** is exposed to the anterior chamber **20** while the outlet end **33** is positioned at about an exterior surface **43** of said diseased trabecular meshwork **21**. In a further embodiment, the outlet end **33** may further enter into fluid collection channels of the existing outflow pathways.

In one embodiment, the means for forming a hole/opening in the trabecular mesh **21** may comprise an incision with a microknife, an incision by a pointed guidewire, a sharpened applicator, a screw shaped applicator, an irrigating applicator, or a barbed applicator. Alternatively, the trabecular meshwork may be dissected off with an instrument similar to a retinal pick or microcurrette. The opening may alternately be created by retrogade fiberoptic laser ablation.

FIG. 7 shows an illustrative method for placing a seton implant at the implant site. An irrigating knife or applicator **51** comprises a syringe portion **54** and a cannula portion **55**. The distal section of the cannula portion **55** has at least one irrigating hole **53** and a distal space **56** for holding a seton implant **31**. The proximal end **57** of the lumen of the distal space **56** is sealed from the remaining lumen of the cannula portion **55**.

For positioning the seton **31** in the hole or opening through the trabecular meshwork, the seton may be advanced over the guidewire or a fiberoptic (retrograde). In another embodiment, the seton is directly placed on the delivery applicator and advanced to the implant site, wherein the delivery applicator holds the seton securely during the delivery stage and releases it during the deployment stage.

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) self sealing incision is made. Through the cornea opposite the seton placement site, an incision is made in trabecular meshwork with an irrigating

knife. The seton **31** is then advanced through the cornea incision **52** across the anterior chamber **20** held in an irrigating applicator **51** under gonioscopic (lens) or endoscopic guidance. The applicator is withdrawn and the surgery concluded. The irrigating knife may be within a size range of 20 to 40 gauges, preferably about 30 gauge.

From the foregoing description, it should now be appreciated that a novel approach for the 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.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An implant for treating an ocular disorder, comprising:

an inlet portion configured to extend through a portion of a trabecular meshwork of an eye; and

an outlet portion configured to extend into Schlemm's canal of said eye;

wherein the outlet portion has at least one protrusion configured to exert traction against an inner surface of Schlemm's canal, the protrusion extending from the implant in a direction substantially perpendicular to a long axis of Schlemm's canal.

2. The implant of claim 1, wherein the protrusion comprises at least one barb.

3. The implant of claim 1, wherein the protrusion comprises at least one ridge.

4. An implant for treating an ocular disorder, comprising:

an inlet portion configured to extend through a portion of a trabecular meshwork of an eye;

an outlet portion configured to extend into and along Schlemm's canal of the eye;

wherein the implant provides a flow path between an anterior chamber of the eye and Schlemm's canal, and wherein said implant has a retention protrusion configured to anchor the implant and stabilize at least a portion of the flow path through the implant.

5. The implant of claim 4, wherein the implant has no cutting surfaces such that the implant is insertable into Schlemm's canal without the implant cutting tissue.

6. The implant of claim 4 or 5, wherein the retention protrusion comprises a barb.

7. The implant of any one of claims 4 to 5, wherein the retention protrusion is on the outlet portion.

8. An implant for treating an ocular disorder, comprising:

a body having an inlet section, an outlet section, a lumen extending between the inlet section and the outlet section,

wherein the body has a longitudinal axis,

wherein the inlet section is configured to be positioned in an anterior chamber of an eye, and

wherein the outlet section is configured to be positioned into an existing outflow pathway of the eye and the outlet section comprise a ridge protruding generally radially outwardly relative to the longitudinal axis of the body.

9. The implant of claim 8, wherein the body has a length in the range from about 3 mm and about 10 mm.

10. The implant of claim 8 or 9, wherein the outlet section comprises two or more ridges.

11. The implant of any one of claims 8 to 10, wherein the implant further comprises at least one opening located on the outlet section.

12. The implant of any of claims 8 to 11, wherein the body comprises polyimide material.

13. The implant of any of claims 8 to 12, wherein the body has an outer diameter in the range from about 200 microns to about 500 microns.

14. An ocular implant, comprising:

a body having a first end portion configured to be positioned in an anterior chamber of an eye when implanted, the first end portion comprising at least one inlet opening and having a first axis defined therethrough, and a second end portion configured to be positioned in a physiologic outflow pathway of the eye when implanted, the second end portion comprising at least one outlet opening and having a second axis defined therethrough, wherein the at least one inlet opening and the at least one outlet opening are in fluid communication;

an anchor disposed on the second end portion configured to be positioned in the physiologic outflow pathway and extending substantially perpendicularly to the second axis without extending beyond the physiologic outflow pathway; and

a therapeutic agent.

15. The implant of claim 14, wherein the body comprises a tube.

16. The implant of claim 14 or 15, wherein the body has a lumen with an oval cross-section.

17. The implant of any one of claims 14 to 16, wherein the at least one outlet opening comprises two outlet openings positioned in the body such that the anchor is located between the outlet openings.

18. The implant of any one of claims 14 to 16, wherein the at least one outlet opening comprises two outlet openings and one of the outlet openings is located substantially at an intersection between the first and second end portions.

19. The implant of any one of claims 14 to 18, wherein the first axis is substantially perpendicular to the second axis.

20. The implant of any one of claims 14 to 19, wherein the anchor extends on plural sides of the body.

21. The implant of any one of claims 14 to 20, wherein the therapeutic agent is part of the body of the implant.

22. The implant of any one of claims 14 to 21, wherein the body is coated with the therapeutic agent.

23. The implant of any one of claims 14 to 22, wherein the body includes a first portion and a second portion that is appended from the first portion, and wherein the first portion includes a lumen and the second portion carries the therapeutic agent.

24. The implant of any one of claims 14 to 23, wherein the at least one outlet opening comprises multiple outlet openings.

25. An implant for treating an ocular disorder, comprising:

a body having a first end and a second end and a fluid flow path defined between at least one inlet and one outlet, said body including at least two regions each having a cross-sectional size smaller than adjacent regions on the implant, said at least two regions being disposed remote from the second end between at least some of the inlets and outlets, said body configured to conduct fluid from an anterior chamber of an eye to a physiologic outflow pathway of the eye,

wherein said second end is sized and shaped to be inserted into and along a portion of a length of the physiologic outflow pathway of the eye, and

wherein said second end is tapered.

26. The implant of claim 25, wherein at least one of the outlets is intermediate the first and second ends of the body.

27. The implant of claim 25 or 26, wherein the implant comprises a therapeutic drug.

28. The implant of claim 27, wherein the body includes a first portion and a second portion that is appended from the first portion, and wherein the first portion includes a lumen and the second portion carries the therapeutic drug.

29. The implant of claim 27, wherein at least a portion of the body is coated with the therapeutic drug.

30. The implant of claim 27, wherein the body comprises a biocompatible material with the therapeutic drug coated thereon.

31. The implant of any one of claims 25 to 30, wherein the implant comprises a polymer.

32. The implant of any one of claims 25 to 31, wherein the adjacent regions comprise ridges protruding radially outwardly from the outer surface of the body.

33. The implant of any one of claims 25 to 32, wherein the at least two regions comprise circumferential regions.

34. The implant of any one of claims 25 to 33, wherein the physiologic outflow pathway comprises Schlemm's canal of the eye.

35. The implant of any one of claims 25 to 33, wherein the physiologic outflow pathway comprises an aqueous collector channel of the eye.

36. The implant of any one of claims 25 to 35, wherein at least a portion of the body is tubular.

37. The implant of any one of claims 25 to 36, wherein at least a portion of the body is elongated.

38. An implant for treating an ocular disorder, comprising:

an elongated body having an inlet end and an outlet end, the elongated body configured to extend through a tissue of an eye such that the inlet end resides in an anterior chamber of the eye and the outlet end resides in and along a portion of a length of a physiologic outflow pathway of the eye; and

an inner lumen within the elongated body, the lumen having an inlet port and an outlet port for providing a fluid flow pathway through the elongated body;

wherein the elongated body comprises at least two regions each having a cross-sectional dimension greater than adjacent regions of the elongated body, said at least two regions disposed remotely of said outlet end; and

wherein said outlet end is tapered.

39. The implant of claim 38, wherein at least a portion of the elongated body is tubular.

40. The implant of claim 38 or 39, wherein the at least two regions extend circumferentially around the elongated body.

41. The implant of any one of claims 38 to 40, wherein the at least two regions each comprise a ridge extending outward from an outer surface of the elongated body.

42. The implant of any one of claims 38 to 41, wherein the at least two regions are disposed on the elongated body between the inlet end and the outlet end.

43. The implant of any one of claims 38 to 42, wherein the outlet end has a uniform taper.

44. An implant for treating an ocular disorder, comprising:

a body of biocompatible material sized and shaped to facilitate the transport of aqueous humor from an anterior chamber of an eye to and within Schlemm's canal of the eye, the body comprising first and second lumens, each of which bypasses a trabecular meshwork of the eye and terminates in Schlemm's canal, so as to receive aqueous humor from the anterior chamber and transport said aqueous humor into Schlemm's canal.

45. A system for treating an ocular disorder, comprising:

a delivery device, the delivery device comprising a handpiece and an elongate delivery member; and

an ophthalmic drainage implant which, following implantation at an implantation site, conducts fluid from an anterior chamber of an eye to an outflow pathway of the eye, the implant comprising:

a body having a proximal section and a distal section with respect to the handpiece of the delivery device, the proximal section comprising an inlet and the distal section comprising at least one outlet, the body having a maximum cross-sectional dimension sized to allow insertion of the body through a self-sealing opening in the eye to access the anterior chamber; and

a lumen extending through the body from the inlet of the proximal section to the at least one outlet of the distal section, the lumen defining a wall thickness of the body;

wherein a distal end of the distal section of the body is tapered;

wherein at least a portion of the lumen of the ophthalmic drainage implant receives at least a portion of the elongate delivery member in an orientation such that the distal section leads the proximal section;

wherein the elongate delivery member is configured for ab interno insertion of the ophthalmic drainage implant through the self-sealing incision and sized to extend across the anterior chamber; and

wherein the ophthalmic drainage implant has sufficient length between the proximal section and distal section such that, upon implantation, at least a portion of the proximal section of the ophthalmic drainage implant is disposed within the anterior chamber and at least a portion of the distal section of the ophthalmic drainage implant extends into and along a portion of the outflow pathway of the eye.

46. The system of claim 45, wherein the body further comprises one or more retention features.

47. The system of claim 46, wherein the one or more retention features comprise protrusions extending radially outwardly from the body.

48. The system of claim 45, wherein the one or more retention features are selected from the group consisting of stubs, ribs, pillars, textured surfaces, threads, flanges, and barbs.

49. The system of any one of claims 45 to 48, wherein the elongate delivery member of the delivery device is flexible.

50. The system of any one of claims 45 to 49, wherein the body comprises more than one outlet.

51. The system of any one of claims 45 to 50, wherein the elongate delivery member of the delivery device comprises a wire.

52. The system of any one of claims 45 to 51, wherein the body is formed of polyimide.

53. The system of any one of claims 45 to 52, wherein the body has a generally tubular shape.

54. The system of any one of claims 45 to 53, wherein the elongate delivery member further comprises a cutting member configured to form an opening.

55. A system for treating an ocular disorder, comprising:

a delivery device comprising a guidewire, the guidewire having a distal end adapted to form an opening in ocular tissue; and

an elongated implant comprising an inlet section, an outlet section, and a lumen therebetween,

wherein the implant is configured to be advanced over the guidewire and introduced into the opening formed in the ocular tissue by the guidewire.

56. The system of claim 55, wherein the distal end is pointed.

57. The system of claim 55 or 56, wherein the implant comprises a polyimide material.

58. The system of any one of claims 55 to 57, wherein the ocular tissue is trabecular meshwork tissue.

59. The system of any one of claims 55 to 57, wherein the inlet section of the implant is configured to be positioned within an anterior chamber of the eye and the outlet section is configured to be positioned within an existing outflow pathway of the eye, thereby providing aqueous humor outflow from the anterior chamber to the existing outflow pathway through the lumen of the implant.

60. The system of any one of claims 55 to 59, wherein the outside diameter of the implant is between 200 microns and 500 microns.

61. The system of any one of claims 55 to 60, wherein the length of the implant is in the range from about 3 mm and to about 10 mm.

62. The system of any one of claims 55 to 61, wherein the guidewire is configured to enter the eye through a corneal incision.

63. The system of any one of claims 55 to 62, wherein the outlet section of the implant comprises a circumferential ridge.

64. An ocular implant, comprising:

a body comprising a biocompatible material and a therapeutic drug;

the body having an inlet portion and an outlet portion;

the inlet portion being configured to reside in an anterior chamber of an eye;

the outlet portion being sized and shaped to be disposed in a physiologic outflow pathway of the eye when the inlet portion is in the anterior chamber; and

the outlet portion having an outflow opening such that the body drains fluid from the anterior chamber to the physiologic outflow pathway.

65. The implant of claim 64, wherein the body has a sufficient length to extend from the anterior chamber into Schlemm's canal.

66. The implant of claim 64 or 65, wherein the outlet portion is sized and shaped to be disposed in Schlemm's canal.

67. The implant of claim 64 or 65, wherein the outlet portion is sized and shaped to be disposed in a fluid collection channel.

68. The implant of clam 64 or 65, wherein the outlet portion is sized and shaped to be disposed in an aqueous vein.

69. The implant of any one of claims 64 to 68, wherein at least a portion of the body is coated with the therapeutic drug.

70. The implant of any one of claims 64 to 69, wherein the drug comprises heparin.

71. The implant of any one of claims 64 to 70, wherein the body includes a first portion and a second portion that is appended from the first portion, and wherein the first portion includes a lumen and the second portion carries the therapeutic drug.

72. The implant of any one of claims 64 to 71, wherein the implant is substantially L-shaped.

73. The implant of any one of claims 64 to 72, wherein the implant comprises a tubular element.

74. The implant of any one of claims 64 to 73, wherein the implant has at least one lumen.

75. The implant of claim 74, wherein the lumen has a substantially oval cross-section.

76. The implant of any one of claims 64 to 75, wherein the implant comprises a protrusion configured to stabilize the implant in eye tissue.

77. The implant of claim 76, wherein the protrusion extends on plural sides of the body.

78. The implant of claim 76 or 77, wherein the body comprises a second outflow opening such that the protrusion is located between a respective one of the outflow openings.

79. The implant of any one of claims 64 to 78, wherein at least a portion of the implant is elongated.

80. The implant of any one of claims 64 to 79, wherein the biocompatible material comprises Silastic™.

81. The implant of any one of claims 64 to 79, wherein the biocompatible material comprises Pellethane™.

82. Use of the implant and/or system of any one of claims 1 to 81 within any eye.

83. Use of the implant and/or system of any one of claims 1 to 81 within an eye.

84. Use of the implant and/or system of any one of claims 1 to 81 for treating glaucoma.

85. Use of the implant and/or system of any one of claims 1 to 81 for reducing or lowering intraocular pressure of an eye.

86. Use of the implant and/or system of any one of claims 1 to 81 for treating an ocular disorder.

87. Use of the implant and/or system of any one of claims 1 to 81 for treating an ophthalmic condition.

88. Use of the implant and/or system of any one of claims 1 to 81 to allow for flow of aqueous humor from an anterior chamber of an eye to Schlemm's canal of an eye.

89. Use of the implant and/or system of any one of claims 1 to 81 to allow for fluid drainage from an anterior chamber of an eye to an existing, physiologic or physiological outflow pathway of the eye.

90. Use of the implant and/or system of any one of claims 1 to 81 to allow for fluid flow to an existing, physiologic or physiological outflow pathway of an eye.

91. Use of the implant and/or system of any one of claims 1 to 81 for placement of the implant within a trabecular meshwork of an eye.

92. Use of the implant and/or system of any one of claims 1 to 81 for placement of the implant in fluid communication with an existing, physiologic or physiological outflow pathway of an eye.

93. Use of the implant and/or system of any one of claims 1 to 81 for bypassing diseased trabecular meshwork and restore existing outflow pathways.

94. Use of the implant and/or system of any one of claims 1 to 81 to allow flow of aqueous humor from an anterior chamber of an eye to an existing, physiologic or physiological outflow pathway of an eye.

95. Use of the implant and/or system of any one of claims 1 to 81 for therapeutic treatment of an eye by providing a drug into the eye.

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Unscannable items received with this application
(Request original documents in File Prep. Section on the 10th floor)

Documents reçu avec cette demande ne pouvant être balayés
(Commander les documents originaux dans la section de la préparation
des dossiers au 10ième étage)

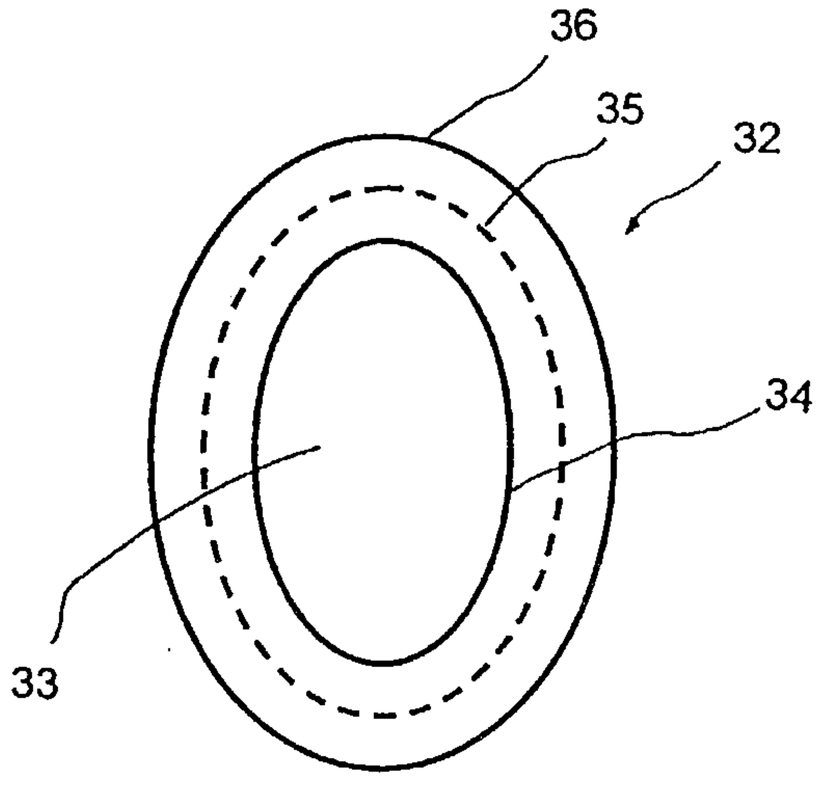

FIG. 4